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IN THIS ISSUE

Malaysia's new draft code aims for ethical marketing, advertising .....Page 3

International quality assurance initiative launches in India.....Page 3

Stakeholders eye future of surveillance.....Page 3

FDA dings Terumo Medical with warning letter for procedural failures ...Page 4

Innovative Sterilization Technologies hit with FDA warning letter over procedural violations .....Page 5

Process validation concerns lead to warning letter for SureTek Medical .....Page 5

A tense situation: An inside take on dealing with difficult inspections .....Page 7

ECRI, LSE join forces to examine device pricing in multiple countries ....Page 8

Senate bill proposes to improve innovation .....Page 8

Reprocessing concerns slow debate over European device regulations ....Page 9

FDA Proposes Ban on Powdered Medical Gloves

The FDA is eyeing a ban on most powdered gloves in the U.S., as the agency says they pose unreasonable and substantial risks that cannot be corrected through new or updated labeling.

If finalized, the ban — which the agency has recommended in a proposed rule — would apply to powdered surgeon's gloves, powdered patient examination gloves and absorbable powder for lubricating a surgeon's glove.

The proposal follows a request for comments in *Draft Guidance for Industry and FDA Staff: Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder*, which was issued in February 2011.

That document proposed a general voluntary warning; however, as agency officials reviewed the comments received, they determined that a ban on powdered gloves is appropriate and decided not to finalize the draft guidance. Last May, the FDA withdrew the draft

(See **Gloves**, *Page 2)*

Sequenom Appeals to SCOTUS for Patent Exclusivity on 'Natural Phenomenon' Invention

Sequenom is asking the U.S. Supreme Court to revisit an earlier decision on the limits of patent eligibility.

The San Diego-based company filed a petition March 21, pushing the High Court to reconsider a 2012 ruling that invalidates the company's '540 patent for a prenatal diagnostic on the grounds that it relied too heavily on a natural phenomenon. The FDA-approved diagnostic detects fetal genetic conditions.

Driving the petition is the precedent established in *Mayo Collaborative Services. v. Prometheus Labs*, a decision that held that inventions involving only a "natural phenomenon" and "conventional" activity cannot be patented.

(See **Sequenom**, *Page 2)*

Gloves, *from Page 1*

guidance as part of an effort to remove documents issued before 2014 that had not been finalized.

The ban is a long time in coming, at least according to Public Citizen. In 1998, the consumer group submitted a citizen petition requesting a ban on the use of cornstarch powder in the manufacture of latex surgeon and patient examination gloves. The agency denied the petition.

"The fact that it took the FDA 18 years to propose banning powdered surgical gloves from the market highlights how recklessly negligent the agency is," says Sidney Wolfe, founder and senior adviser of Public Citizen's health research group.

The FDA acknowledges that scientific evidence in 1998 indicated glove powder was associated with negative health consequences. However, certain factors weighed against removing the devices from the market at the time, including quality concerns, the lack of suitable alternatives and costs.

Between 2008 and 2011, the FDA received three petitions seeking a ban on the use of cornstarch powder on natural rubber latex and synthetic latex surgical and examination gloves. The petitions, including one from Public Citizen in 2011, prompted the agency to evaluate new data on the risks of using powdered gloves and consider new information on alternatives.

The FDA says it conducted an economic analysis showing a powdered glove ban would not lead to a shortage, and the economic impact of a ban would not be significant.

The ban also probably wouldn't affect medical practice, as there are many non-powdered protective glove options available.

Non-powdered surgeon gloves and non-powdered patient examination gloves will remain Class I devices.

Comments are due June 20. Read the proposed rule here: www.fdanews.com/03-21-16-FDAGloves.pdf. — Jonathon Shacat

Sequenom, *from Page 1*

"*Mayo v. Prometheus* does not create any problems for traditional drugmakers, but it is wreaking havoc in the market for diagnostic testing, treatment regimens and personalized medicine. The case will see strong support from industry, and I believe has a good chance for Supreme Court review," Dennis Crouch, associate professor of law at the University of Missouri School of Law, tells *IDDM*.

Mayo was the driving force that led a three-judge panel from the U.S. Court of Appeals for the Federal Circuit to uphold a ruling invalidating the '540 patent. Sequenom challenged Ariosa Diagnostics on the basis of its patent; however, the court ruled that even though the invention "revolutionized prenatal care," the court was bound by *Mayo* to reject the patent.

The company contends that the circuit court overextended the decision in *Mayo*. It refers to the Supreme Court's two-part test as part of its decision, which asks whether the patent incorporates any excepted categories under U.S. patent law — such as a natural law — and whether the "patent claims add enough … to allow the processes they describe to qualify as patent-eligible processes that apply natural laws."

Sequenom is calling on the high court to "clarify" *Mayo's* reach and answer whether a novel method is patent eligible if:

- A researcher is the first to discover a natural phenomenon;
- That unique knowledge motivates the researcher to apply a new combination of known techniques to that discovery; and
- The researcher achieves a previously impossible result without preempting other uses of the discovery.

Read the petition here: www.fdanews.com/03-22-16-SequenomCertiorariPetition.pdf. — Michael Cipriano

Malaysia's New Draft Code Aims For Ethical Marketing, Advertising

Malaysia's Medical Device Authority is proposing new requirements for advertising and marketing medical devices in the country.

The MDA issued a draft code earlier this month covering materials for a range of marketing vehicles, including billboards, talk shows, direct mail materials and aerial promotion on hot air balloons.

Each ad must contain the manufacturer's name and contact number, the establishment's license number, as well as the device's name and registration number.

Ads also must contain information that is "reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date and be capable of substantiation."

The draft code also spells out requirements covering endorsements by celebrities and healthcare professionals, user testimonials, comparative advertising and other promotional activities.

Further, companies are allowed to issue press releases to announce product launches.

But the use of brand names should be kept to a minimum, and the tone and content should be factual and not sensationalized.

The draft code does not regulate pricing, commercial practices or non-promotional information.

Read the *Code of Advertisement for Medical Devices* here: www.fdanews.com/03-22-16-MDACode.pdf. — Jonathon Shacat

International Quality Assurance Initiative Launches in India

Devicemakers in India may soon obtain quality certification as part of an initiative launched earlier this month.

The Indian Certification of Medical Devices Scheme is the country's first indigenously developed system of its kind.

The scheme features two options for certification – ICMED 9000 (an ISO 9001 plus additional requirements) for low-risk devices and ICMED 13485 (an ISO 13485 plus additional requirements) for medium- and high-risk devices.

A third level, which would introduce device specifications developed by the Health Ministry's National Health System Resource Centre, will be launched later this year.

ICMED is a joint initiative of the Association of Indian Medical Device Industry, Quality Council of India and the National Accreditation Board of Certification Bodies.

The program aims to reduce the time to obtain globally accepted quality certification for Indian companies and eliminate malpractice in substandard or fraudulent certifications or quality audits.

NABCB is accrediting certification and inspection bodies and its accreditation programs are internationally equivalent, placing it on par with European and American accreditation bodies, says CEO Anil Jauhri.

"This equivalence would help facilitate acceptance of ICMED certification in overseas markets," he says.

The certification scheme is open to both domestic and foreign manufacturers, although Indian devicemakers are expected to join initially. — Jonathon Shacat

Stakeholders Eye Future of Medical Device Surveillance

A board working on a nationwide system to monitor the risks and benefits of medical products on the market outlined some of the projects it hopes to undertake to help boost the safety and effectiveness of devices.

Among the projects being considered by the National Evaluation System for Medical Devices board is quantifying potentially serious but rare adverse events in Class 2 devices. This project

(See **Surveillance**, *Page 6)*

FDA Dings Terumo Medical With Warning Letter for Procedural Failures

Terumo Medical has earned an FDA warning letter due to procedural failures for controlling product conformity as well as validating and verifying device design.

The warning letter, dated March 17, stems from an Oct. 19 to 23, 2015, inspection at the firm's Elkton, Md., facility, which manufactures the Destination guiding sheaths for renal, carotid and peripheral use.

The FDA takes Terumo to task for not following procedures for renal guiding sheaths that failed testing. The company also used two bottles of a product to coat renal sheaths without justification.

Terumo also failed to establish and maintain procedures to verify and validate certain tests for device design. In one instance, the results and raw data were missing for testing performed on carotid guiding sheath introducer kits.

In addition, the warning letter says the company failed to adequately implement its validation procedure. "There is no documented evidence to show that the process parameters for the validated processes used in production of the Destination guiding sheaths was monitored by your firm," the FDA says.

Terumo responded to the FDA's Form 483 in four separate letters since November 2015; however, the agency says the responses were inadequate.

In terms of nonconforming product disposition, Terumo described several practices for ensuring that the solution bottles used in production are acceptable, but the FDA says the company did not provide information about how it handles bottles that fail testing.

In other cases, the agency says the company did not provide evidence that it had implemented corrective actions.

Terumo could not be reached for comment by press time. Read the warning letter here: www.fdanews.com/03-22-16-TerumoWarningLetter.pdf. — Jonathon Shacat

Innovative Sterilization Technologies Hit With Warning Letter Over Procedures

Innovative Sterilization Technologies has received an FDA warning letter for failing to establish and maintain procedures when dealing with contract manufacturers.

The March 2 letter takes the company to task for having inadequate procedures for corrective and preventive actions, as well as issues surrounding design controls and complaint processing. All of the complaints stem from inspections of the company's records in Dayton, Ohio between Aug. 4 and 13, 2015, and Oct. 6 through Nov. 4, 2015.

While the company responded to findings on the 483 in August, the warning letter asserts that its proposed changes to the CAPA procedure fails to show the statistical methodology to analyze data sources, or address the agency's request for a retrospective review of the data sources.

Additionally, the letter says that Innovative Sterilization Technologies did not establish design controls for its sterilization container, such as documenting the design method for testing and the actual test results of changes.

In a separate November response letter, IST said it was developing design procedures and had requested validation data from the 510(k) holder. The warning letter requests an update on the company's progress.

The warning letter also contends that none of the 134 warranty repairs the company received between January 2014 and August 2015 were evaluated as possible complaints. In IST's response, the company said it would conduct a retrospective review of all warranty repairs.

In addition, the FDA says IST failed to verify or validate change procedures from switching from a hydroforming process to a numeric control process for contract manufacturing.

Company spokesman Walt Oko says IST has been working with the FDA since the original inspection. "We are not contesting any of their findings. We are actually using them constructively to make our systems better," he tells *IDDM*.

Read the warning letter here: www.fdanews.com/03-17-16-ISTLetter.pdf. — Jonathon Shacat

Process Validation Concerns Lead to Warning Letter for SureTek Medical

An FDA warning letter takes SureTek Medical to task for its procedures related to assessing contamination for reprocessed single-use devices.

The March 3 letter stems from an FDA inspection at the orthopedic and laparoscopic instrument maker's facility in Greenville, S.C., from Oct. 26 to Nov. 10, 2015.

SureTek's validated cleaning process is not routinely monitored to assess contamination levels for reprocessed single-use devices, the FDA says.

The letter states that the most recent assessments for contamination were performed in 2012, even though the firm's procedures call for bioburden monitoring on a quarterly basis.

The company responded to the inspector's Form FDA 483 with letters in December 2015 and February, indicating that bioburden samples for the first quarter of 2016 were scheduled for testing in March. As a result, the FDA requested a copy of the testing results.

SureTek also failed to adequately identify the worst-case product used during the validation of its sterilization process, according to the warning letter. The warning letter requests a copy of the sterilization validation process for verification.

In addition, the agency maintains that the number of samples used in the cleaning validation studies were not statistically adequate. It also says that proposed changes in the company's letters fail to resolve that issue.

SureTek could not be reached for comment by press time. Read the warning letter here: www.fdanews.com/03-17-16-STMLetter.pdf. — Jonathon Shacat

Surveillance, *from Page 3*

would allow experts to link electronic health records and claims data to create a retrospective virtual registry to calculate the rate of these events.

The NESMD board also hopes to enhance existing patient registries to standardize and automate data entry from information collected in EHRs.

In addition, the board wants to promote methods to collect information directly from patients, including safety problems, said Greg Daniel, deputy director of the Duke-Margolis Center for Health Policy at Duke University, during a meeting last week in Baltimore, Md.

The event was jointly sponsored by the FDA and the University of Maryland's Center of Excellence in Regulatory Science and Innovation, which is funded by the agency to help improve the way drugs and devices are reviewed.

A Vacuum

Discussions about the board's plans come in the wake of a number of medical device-related adverse events, including complaints about metal-on-metal hips and the Essure implantable birth control product. A national system to collect relevant information about medical devices in the postmarket setting would go far toward identifying safety signals earlier and prevent patient harm, CDRH Director Jeffrey Shuren said.

Additional information also would give patients guidance in terms of what devices can help them. Millions of people are living with implanted devices, said Fadia Tohme-Shaya, of the University of Maryland School of Pharmacy; however, a paucity of information as a result of ineffective data generation in clinical trials has discouraged millions of others from obtaining them.

"The lynchpin here is evidence generation," Shuren emphasized, adding that establishing the NESMD is one of the center's strategic priorities for 2016 and 2017 (*IDDM*, Jan. 15). Shuren provided some color on the "learning medical device ecosystem," which would replace the passive surveillance system that exists now.

The NESMD would place an emphasis on gathering more data in the postmarket setting through unique device identifiers, EHRs and registries. These data can help devicemakers, which struggle with subject enrollment for postmarket trials, as patients aren't incentivized to sign up for these studies.

To gain access to evidence, stakeholders have proposed developing a coordinated network to generate usable data.

The network would revolve around a coordinating center, which would serve as a source of safety updates, recall management and effectiveness information, Daniel said.

Shuren said the selection of a coordinating center was pending the outcome of the user fee negotiations. — Elizabeth Hollis

A Tense Situation: An Inside Take on Dealing With Difficult Inspections

Dealing with tense inspections can be challenging, but learning what to do in real-world scenarios can help firms prepare. Steve Niedelman, lead quality systems and compliance consultant at King & Spalding and former FDA deputy associate commissioner for regulatory operations, and Elaine Messa, president of the Medical Device Practice at NSF Health Sciences and former director of the Los Angeles District at the FDA, provided advice on the topic during the FDAnews' Medical Device Quality Congress on March 16.

Q: An investigator arrives at a U.S. facility on Dec. 26 for an unannounced inspection and is upset because no one is available to immediately start the inspection. How do you respond, and what actions can you take?

Niedelman: You should start calling employees and tell them to come to work. Explain that it will take a while for some of them to arrive, but you will do your best to accommodate them. As long as you are open for business, the FDA has the right to inspect.

Q: A team of investigators shows up to conduct a preannounced inspection. One investigator, who has the Notice of Inspection (FDA-482), gets lost on the way to the firm and arrives late. The investigators want to begin the inspection before his arrival. What do you do?

Niedelman: Apologize to the investigators, but insist that they need to present the Notice of Inspection first, because it is the legal document that provides the right to inspect. An adversarial situation can be avoided easily by offering them a seat and some coffee.

Q: During an inspection to verify the effectiveness of a sub-recall, an overly aggressive and untrusting male FDA investigator follows a female employee to the women's restroom. When he overhears talking taking place in the restroom, he grows suspicious of the employee's actions, opens the door to the restroom, steps inside and tells the employee she is not permitted to use her cell phone to call anyone. What should the employee do? How should the company respond?

Niedelman: Explain that it is inappropriate behavior for a male investigator to walk into the women's restroom. Besides, they don't have the right to tell you not to use your cell phone. In fact, you can use your cell phone in front of them, and there is nothing that stops you from doing that.

Q: During a tour of the manufacturing operation, the investigator decides to question the line operators. One operator in particular is visibly nervous and does not respond to the investigator's direct questions promptly and his responses are not completely accurate. The investigator claims the operator is not trained and is possibly hiding information. How do you respond?

Messa: Explain to the FDA investigator that people can get nervous even if they are trained.

Niedelman: Show documented training records to prove that the operator is well trained. Companies also can conduct mock inspections to get employees prepared for these kinds of situations.

Q: An investigator has identified a potential FDA-483 observation during an inspection at your firm. He approaches you with a "Management Commitment to Correct" that he has prepared for your signature, promising that if it is signed, the items will not be included on the FDA-483. Do you sign the Management Commitment to Correct?

Niedelman: You should not sign it because the "Management Commitment to Correct" is not an official FDA form.

Q: The firm decides to decline signing the Management Commitment to Correct. The investigator advises management he has "all the time in the world" to sit in the conference room and wait until they decide to sign the document. What do you do?

(See **Q&A***, Page 8)*

Q&A, *from Page 7*

Niedelman: You should negotiate. Tell the investigator that you are not going to sign it and that he won't change your minds if he stays there all night.

Q: During a tour of the manufacturing facility, the investigator takes out his smartphone and begins taking pictures with no explanation. How do you respond? Do you permit him to take pictures? Conversely, how do you prevent the action? Should you be concerned that the investigator is using his smartphone?

Messa: Many companies don't want anybody taking photographs of proprietary information and equipment. I strongly recommend posting signs saying that photography is not permitted.

Niedelman: Most firms have a "no photograph" policy and it should be introduced during the opening presentation. Investigators have government-issued cameras, and they shouldn't be using their personal smartphones in this age of social media.

ECRI, LSE Join Forces to Examine Device Pricing in Multiple Countries

ECRI Institute is partnering with the London School of Economics to examine medical device pricing.

The pair will analyze pricing trends in France, Germany, Italy, the UK and the U.S. They will look at specific device categories, rather than individual manufacturers.

Products will range from everyday items to complex and high-risk implantables, explains David Watson, vice president for operations at ECRI Institute Europe.

The project will use ECRI Institute's PriceGuide, a comprehensive medical-surgical supply and implant procurement advisory service with pricing on nearly 1.5 million medical/surgical supplies and implants.

Device-related spending is concentrated in cardiac and orthopedic specialties, where expensive implantables are chosen by physicians, he says. These devices are referred to as "physician preference items."

"Little is known about factors that determine prices of PPIs, and some studies suggest that prices, usually included in case-based payments to hospitals, may vary significantly between countries and between different hospitals in the same country," he tells *IDDM*. — Jonathon Shacat

Senate Bill Proposes to Improve Device Innovation

Two lawmakers have proposed legislation that aims to improve the operational effectiveness at the FDA.

A Bill to Improve Medical Device Innovation (S. 2737) — introduced March 17 by Sens. Amy Klobuchar (D-Minn.) and Pat Roberts (R-Kan.) — would give the FDA the authority to eliminate the premarket submissions requirement for a small set of low-risk, Class I products. It has been referred to the HELP committee.

The bill would update the law to give the agency the authority to no longer require premarket submissions for a small set of low-risk, Class I products, if the FDA deems it appropriate, says JC Scott, senior executive vice president of government affairs at AdvaMed.

In praising the bill, Scott says it would promote transparency in selecting panel members for FDA advisory committees.

It would also give the agency the authority to pilot alternative methods for improving adverse event reporting.

All of the provisions except the adverse event pilot provision were part of the 21st Century Cures Act (*IDDM*, July 10, 2015).

The "postmarket pilot to improve medical device reporting" provision would allow the FDA to run pilot projects with voluntary participation by manufacturers.

Read the bill here: www.fdanews.com/03-25-16-Bill2737.pdf. — Jonathon Shacat

Verathon Recalls GlideScope Single-Use Video Laryngoscope

Verathon is recalling its GlideScope Titanium single-use video laryngoscope in the U.S. due to a potential video feed disruption.

The recall, designated as Class I by the FDA, involves 6,377 units manufactured from November 2014 to December 2015, and distributed between Nov. 14, 2014 and Dec. 29, 2015. The GlideScope is used to get a clear look at vocal chords and to aid in inserting a tracheal tube.

A disrupted or unstable video image may lead to delayed tracheal tube insertion, intubation failure and other serious adverse events, including death, according to the FDA.

Verathon sent a recall letter to customers Jan. 29 instructing them to either return or destroy affected products.

A company spokesperson tells *IDDM* that the recall is ongoing.

Read the FDA's recall notice here: www.fdanews.com/03-21-16-VerathonRecall.pdf.
— Jonathon Shacat

Reprocessing Concerns Slow Debate Over European Device Regulations

European officials are roughly 90 percent of the way toward reaching an agreement on new regulations for medical devices and in vitro diagnostics, but there are still points of contention, according to one expert.

Among the roadblocks is disagreement over the reprocessing of single-use devices, according to Paul Brooks, senior vice president of healthcare solutions at BSI. Brooks expects the regulation will provide a framework allowing member states to choose to either permit or prohibit the activity.

Under the proposal, reprocessors would be considered as re-manufacturers, meaning they would need to take responsibility for CE marking and compliance in the marketplace. However, hospitals that conduct in-house reprocessing may be allowed to deviate from the requirements, he said.

Proposed regulations also call for a scrutiny process for Class 3 implantable devices, requiring notified bodies to send CE certificates to an expert panel for review before they can make a decision on issuing a CE mark. Industry is concerned that the process could cause delays, creating less predictable clearance of the devices, Brooks said.

Industry is lobbying over a potential requirement for notified bodies to review Class 2b implants, effectively giving them a level of scrutiny normally reserved for Class 3 products. Industry is concerned the requirement could overwhelm the notified body system, which is already quite stretched.

"It's getting much more difficult to be a notified body, and it's going to be more difficult to be a notified body going forward," said Brooks. Devicemakers are facing steep challenges due to a decline in the numbers of notified bodies, and industry is already seeing a culling of the weakest bodies (*IDDM*, March 11).

Trialogue Discussions

The European Council approved the proposed regulations last year, paving the way for it to begin trialogue discussions with the European Commission and Parliament (*IDDM*, June 19, 2015).

It was hoped the trialogue would conclude by Easter, but now it seems more likely that will occur in June, said Brooks. "Just because we have an agreement, doesn't mean we have regulations," he said during the FDAnews Medical Device Quality Congress earlier this month in Rockville, Md.

"Our best guess at BSI is that the earliest we can expect to see the regulations enter into force is the end of this year or the early part of next year," he said. Even then, a transition period would give devicemakers three years and in vitro diagnostic manufacturers five years to comply.
—Jonathon Shacat

BRIEFS

SRS Medical Nabs Approval in South Korea

The Korean Food and Drug Administration has granted approval to SRS Medical Systems' Spanner temporary prostatic stent. The device is intended to relieve lower urinary track symptoms in patients in temporary urinary retention, the company says. The Spanner has FDA approval for a single 30-day period in a limited population. In addition, the device has been approved in Saudi Arabia and received IDE approval from the FDA in January.

Physio-Control Recalls AED Electrodes

Physio-Control has announced a recall of specific lots of its Quik-Combo adult pacing/defibrillation/ECG electrodes and its Red-Pak preconnected system due to possible damage to the wire insulation during the manufacturing process. The company asks that customers quarantine and return any unused products, according to a safety notice. No complaints related to the issue have been received, the safety notice adds. However, using a damaged product could result in an increased risk for reduced or no patient therapy, arcing of current, sparking or patient or clinician burns.

bioLytical Develops Zika Test

bioLytical Laboratories has developed a preclinical prototype assay to detect Zika antibodies in patient samples collected shortly after the onset of symptoms. The prototype is developed on the company's INSTI rapid test platform, which is capable of providing results in as little as 60 seconds. The preclinical test successfully detected Zika antibodies from infected patient serum or plasma with minimal cross-reactivity with confirmed positive Dengue or Chikungunya sera.

B. Braun, ICU Medical Enter Deal

ICU Medical has reached a long-term distribution agreement through which B. Braun will market ICU's SwabCap disinfecting cap for needleless connectors. Under the agreement, B. Braun will gain distribution rights to promote SwabCap in more than 30 countries outside the U.S. SwabCap is disposable and intended to disinfect needleless connectors while improving the barrier to bacterial ingress and refining visual swabbing compliance, the company says. Financial terms of the deal were not disclosed.

Clarius Introduces Ultrasound Scanner

Clarius Mobile Health has unveiled the first mobile ultrasound scanner, with an application for iPhone and Android devices, at the American Institute of Ultrasound in Medicine Conference. Clarius is offering a number of scanners for the price of a traditional compact system, which ranges from $25,000 to $70,000, according to the company. The scanner is awaiting clearance from the FDA, as well as sign-offs in Europe and Canada.

Boston Scientific Introduces AXIOS System

Boston Scientific has launched its AXIOS stent and electrocautery enhanced delivery system, indicated to manage pancreatic pseudocysts and walled-off pancreatic necrosis. The lumen-apposing, expandable stent aids in the drainage of pancreatic fluid collections and reduces the risk of leakage and migration, the company says. AXIOS is the only removable metal stent in the U.S. intended for PFC drainage. The system lowers costs by minimizing procedural time, length of hospital stay and X-ray exposure.

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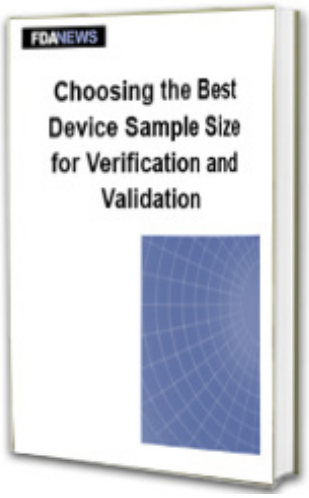

Choosing the Best Device Sample Size for Verification and Validation

If you're like many manufacturers, you understand the essence of the *21 CFR 820.30* requirement: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. And, like many manufacturers, you've probably had trouble for years determining exactly how many units of a product you should test to satisfy the FDA.

Choosing the Best Device Sample Size for Verification and Validation will help you select the right statistical methods to make this determination. With it, you'll learn how to get the right sample size to ensure that user requirements are met in the product design. This management report will also help you understand how to:

- Examine the discrete or continuous statistical data you collect.
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Root Cause Analysis for Drugs and Devices

This management report provides a step-by-step guide to conducting an effective root cause analysis, from recognizing problems that need to be investigated to documenting the investigation so regulators can see you are on top of the situation. Along the way, you'll learn about:

- Gathering the right people to conduct the investigation;
- Developing an accurate problem statement;
- Identifying problems that should trigger CAPAs;
- Various analytical tools that can help narrow the focus of your investigation, including:
  - o Affinity diagrams;
  - o Fishbone diagrams;
  - o GANTT charts;
  - o Trend analysis;
  - o Pareto analysis; and more.
- Documenting the effort in detail; and
- Understanding regulators' requirements and avoiding consequences, such as 483s and Warning Letters.

The report also includes root cause analysis templates readers can customize for their own investigations, including:

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