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Guidance Outlines Risk-Benefit Factors Used in FDA Enforcement Decisions

When the FDA considers an enforcement action for a medical device, there are a variety of benefit-risk factors that can affect its decision — and possibly lead to enforcement discretion, according to a new draft guidance.

If the FDA conducts a benefit-risk assessment and finds the device has a high benefit to patients and the compliance issue causes little risk, it may decide to work with a company informally, rather than taking an official enforcement action like a warning letter.

The FDA may also use the benefit-risk assessment to decide if a company's proposed correction strategy is adequate.

Manufacturers can use the same benefit-risk factors when choosing their responses to nonconforming product or compliance issues, the guidance says. This can include deciding whether to conduct a recall or take other actions that might affect device availability.

(See **Risk-Benefit**, *Page 2)*

FDA Beefs-up ISO 10993-1 Guidance Via Risk-Based Approach

FDA is incorporating a risk-based approach for analyzing biocompatibility of medical devices that come into direct or indirect contact with the body.

The FDA's final guidance provides specifics on how to conduct a biocompatibility assessment using the International Organization for Standardization (ISO)-10993. The document updates April 2013 guidance.

When assessing new devices, the sponsor should state if the device has direct or indirect tissue contact to determine if further biocompatibility testing is needed.

Similarly, when assessing device modifications, the sponsor should clarify if a modification results in a change to direct or indirect

(See **ISO 1993-1**, *Page 4)*

Risk-Benefit, *from Page 1*

When the FDA assesses device benefits, it considers the:

- Type of benefit, such as impact on survival, improved patient function or symptom relief;
- Likelihood of patients experiencing benefits;
- Duration of effects;
- Patient preference, which is the value that patients place on the device;
- Benefits for healthcare professionals or caregivers; and
- Medical necessity.

"Benefit considerations should include an assessment of whether another medical device or therapy could be used in substitution, and the availability of that other medical device or therapy," the guidance says. The assessments may help the FDA decide whether a product correction would be better than a removal, and how to manage access to a nonconforming device during a shortage.

Benefit factors may need to be reassessed at later points in the product lifecycle, after a device is widely used.

The guidance also discusses risk considerations, which include the:

- Severity, categorized into three levels: deaths or serious injuries, non-serious events or events without reported harm;
- Likelihood of risk;
- Nonconforming product risks, such as how many nonconforming devices are on the market;
- Duration of exposure;
- False-positive or false-negative results;
- Patient acceptance of risk; and
- Risk factors for healthcare professionals.

The scope of the device issue should also be evaluated to see whether the risks could be present in similar devices, the guidance says.

Like benefits, the risk factors may need to be reassessed later in the product life cycle after the device is widely used. Manufacturers should note any changes in risk in their risk-management documentation, the guidance says. These changes may involve unanticipated harm to patients exposed to the device, changes in the use environment, nonconformities, or issues related to design or manufacturing.

FDA assessments may consider additional factors including uncertainty, mitigations, detectability, failure mode, patient impact, nature of violations/nonconforming product and company compliance history.

In addition to compliance decisions, the FDA may assess benefit-risk factors during evaluation of device shortages, recalls and inspectional observations during PMA inspections, or when it considers companies' petitions for variance from the quality regulation.

Comments on the guidance are due Sept. 14. The draft guidance is available at www.fdanews.com/06-15-16-FDAGuidanceFactorsBenefit-RiskMedicalDevice.pdf. — April Hollis

FDA Lifts Terumo Consent Decree

Shipping restrictions placed on Terumo Cardiovascular Systems' Ann Arbor facility under a 2011 consent decree have been lifted.

Terumo completed its work plan in February 2016, and the agency reinspected the plant in May and found the firm in full compliance with quality system regulations.

In a June 8 letter, the FDA said Terumo could resume manufacturing, packing, storing, installing, and distributing products from the facility.

The Ann Arbor facility designs and distributes electromechanical devices used in cardiac surgery, including heart-lung machines and blood parameter monitoring systems. The company will resume distribution of its monitoring systems this summer, and it plans to scale up production of its heart-lung machines.

Terumo CVS is one of several subsidiaries of Tokyo-based Terumo Corporation, which recently announced it would acquire Sequent Medical for $280 million. — Joya Patel

Risk Assessment Issues Bring Warning for Laser Sheath Maker

The FDA has warned Spectranetics, a manufacturer of laser sheaths, for issues with its device risk assessments following patient deaths.

Deaths were reported with the GlideLight Laser Sheath/SLS devices beginning in 2014, and the warning letter suggests a higher severity rating in the risk analysis would have been appropriate in light of the deaths and "multiple complaints." The severity rating will be assessed during the next inspection "since risk should be continually reviewed as additional postmarket data becomes available, per your procedures," says the May 23 warning letter.

Spectranetics has multiple risk analysis documents that it can reference to determine risk ratings, but it lacks a set methodology to ensure uniform probabilities are assigned to each risk across the different documents, the letter adds.

Inadequate Process Validation

Validation issues also drew the FDA's attention during the inspection period from Nov. 30, 2015, to Jan. 21, 2016. The company had not validated a process used to manufacture part of the outer jackets subassembly of certain devices.

The company's laser systems include a Class IV laser, and the outer jackets contain the laser. "Complaints have been reported for failures such as cracks, splits, damage to the outer jacket and/or sparks and visible laser light through the outer jacket," the letter says.

Spectranetics' process validation for a process related to the Class III GlideLight and SLS Laser Sheath finished devices was also deemed inadequate because it lacked a component of the company's test protocol requirements.

During the inspection, the FDA found that Spectranetics made changes after an initial protocol was approved. The letter notes that acceptance criteria should be clearly defined before any validation, and any deviations should be evaluated, with justifications of why they may be acceptable. Evaluation of the process and related deviations may require revalidation, the agency says.

The company made another change between the protocol being written and performed, but the investigator did not find an assessment of how the change might affect the finished product. Due to the procedural deficiencies, "several CAPA records are deficient," the letter says.

Multiple Nonconformances

Another citation noted that Spectranetics identified multiple nonconformances, with common cause statements suggesting a potential cause from a certain process. However, the firm did not analyze the common process to identify and prevent further nonconformances.

In addition to being a medical device, Spectranetics' surgical laser systems are "electronic products" and must comply with certain regulations for Electronic Product Radiation Control. However, the company has not submitted Accidental Radiation Occurrence reports for some complaints where the outer jacket of the fiber catheter sheath was damaged, leading to "visible light, sparks and minor burns." The FDA investigator found complaint records that should have been reported as AROs, according to the letter.

The company told *IDDM* it plans to respond to the FDA , and it believes that its response will involve updates in processes and documentation but won't have a material impact on its business. Spectranetics stresses that the warning letter does not require the withdrawal of any product from the marketplace.

"We have already addressed several of the issues brought up in the Form 483's, which were disclosed in our most recent Form 10-K. As a medical device manufacturer we have to report incidents where deaths occur when our devices are used, regardless of the cause of death," Spectranetics told *IDDM*.

Read the warning letter here: www.fdanews.com/06-07-16-Spectranetics.pdf. — April Hollis

ISO 1993-1, *from Page 1*

tissue contact. If a modification would result in direct or indirect contact, a biocompatibility evaluation should be conducted.

The document addresses how to evaluate sterile and non-sterile medical devices that come into contact with the body, including:

- Use of risk assessments for biocompatibility evaluations for a proposed medical device;
- Use of ISO 10993-1 and the FDA-modified matrix to determine relevant biocompatibility endpoints for an evaluation;
- Specific considerations for testing;
- Chemical assessment recommendations; and
- Considerations for labeling devices as "free."

The final guidance provides specific information to include in:

- Device master files for biocompatibility evaluations;
- Summary biocompatibility documentation;
- Biocompatibility evaluation flow charts;
- Biocompatibility test reports; and
- Component and device documentation examples.

The ISO 10993-1 guidance can be found here: www.fdanews.com/06-15-16-FDAGuidanceISO10993-1.pdf. — Joya Patel

General Approach to Biological Safety Evaluations (BSE)

CONSULTATION & GAP ANALYSIS	CHEMICAL CHARACTERIZATION	BIOCOMPATIBILITY	TOXICOLOGICAL RISK ASSESSMENT
Regulatory affairs review of device: • **Predicate** • **Intended Use** • **Label Claims** Pre-Assessment of Toxicological Risks and Development of Biological Safety Test Plan and Justifications	Material: • **Composition** • **Identity** Extractable/Leachable: • **Simulated** • **Exaggerated** Manufacturing residue: ***Anything on the device not intended to be part of the device***	Cytotoxicity Sensitization Irritation Systemic Toxicity *Subacute/Subchronic* Genotoxicity Hemocompatibility *Blood Contact Devices* Implantation *Implanted Devices*	Preparation of final toxicological report: • **Chemical Data** • **Material Data** • **Biological Data** • **Literature Search** • **Product Details** Toxicologist review and sign off for device safety assessment.

Source: MDDI: Medical Device and Diagnostic Industry

Boston Scientific Issues Urgent Field Safety Notice for Pelvic Mesh Products

Boston Scientific has issued updated warnings for 16 of its pelvic mesh products, labeling meshes as permanent implants and warning of complications associated with removal.

The device giant added new directions for use and precautions, warning that regardless of the route of delivery, meshes have been linked to erosion, and treatment of adverse events would require surgical intervention if possible.

"Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications," the new precautions section warns, adding that "the response to these events may persist as a permanent condition after the intervention."

The list of possible adverse events was updated to include: perforation or laceration of vessels, nerves, bladder urethra or bowl may occur during placement, scarring and ongoing pain.

Last year, Boston Scientific was fined $100 million in a pelvic mesh lawsuit. A jury found the company guilty of negligence, failing to warn patients and doctors about possible risks. However, in October, a Delaware judge reduced the fine to $10 million (*IDDM*, June 1, 2015). — Joya Patel

FDA Issues Final Rule On Stand-alone Labeling

The FDA is allowing certain devices to carry stand-alone symbols on labels, in an effort to harmonize international standards used in medical device labeling.

In a final rule issued Tuesday, the agency is offering stand-alone symbols as an alternative to the agency's current standards for medical devices, which allow for either text-only or a combination of text and symbols labeling. The changes seek to make labeling more user-friendly by replacing small and difficult-to-read text with symbols.

The option to use adjacent explanatory text is still available to manufacturers. In another significant change, FDA is now allowing the use of "Rx only" or "℞ only" symbol statements for prescription device labeling.

AdvaMed, the trade association that represents medical device manufacturers, applauded the long-awaited rulemaking. It specifically supported the language on stand-alone symbols, and another provision that would allow flexibility in the types of acceptable symbols devicemakers could use.

"Use of symbols in device labeling can help improve understanding and use of medical devices for both patients and physicians, and the agency's final rule will encourage appropriate use of symbols," Janet Trunzo, AdvaMed's senior executive vice president for technology and regulatory affairs, told *IDDM*.

Streamlining International Labeling Practices

Previously, the FDA had not allowed devicemakers to use symbols in the labeling of their devices, unless they were accompanied by explanatory text — or if the symbol appeared on an in vitro (IVD) device that was being used in a professional capacity.

To harmonize U.S. device labeling requirements for symbols with international regulatory requirements, the medical device industry requested that FDA revise its regulations to allow for the use of stand-alone symbols in domestic labeling for devices.

The final rule sought to bring U.S. device labeling requirements in line with at least three international regulatory mandates: Medical Device Directive 93/42/EEC of the European Union; International Electrotechnical Commission (IEC) standard IEC 60417, and International Organization for Standardization (ISO) standard ISO 7000-DB, which regulates device symbols in a fair number of overseas markets.

U.S., EU Shared Symbols

Under the final rule, an exporter would be able to use the same set of stand-alone symbols on device labeling in the U.S. and the EU. This would save U.S. manufacturers who export medical devices to the EU significant resources associated with designing and redesigning labeling to include symbols with adjacent explanatory text to use in the U.S., according to the FDA.

The agency estimates that annual cost savings could start at more than $7 million and reach as high as $25.5 million, under certain discount rates.

As of Sept. 13, the date this rulemaking goes into effect, medical devicemakers will be able to use symbols in their labeling that incorporate a standard developed by a standards development organization (SDO) in the absence of text as long as the symbol meets requirements under Section 514(c) of the FD&C Act.

In the event a symbol's standard does not meet Section 514(c) specifications or isn't recognized by the FDA, the device maker must show that the average layperson could read and interpret the symbol.

"In addition, in either case, the symbol must be explained in a paper or electronic symbols glossary that is included in the labeling for the medical device," FDA specified in the final rule.

Read the FDA rulemaking here: www.fdanews.com/06-15-16-DeviceLabelingRule.pdf.
— Jennifer Lubell

EU Advances Stricter Device Safety Requirements

Stricter requirements on safety evidence, monitoring and certification for medical devices have won support from members of the EU Parliament's Health Committee.

The measures are intended to improve compliance and traceability in light of issues with breast and hip implants.

"The metal-on-metal hip scandal highlighted weaknesses in the current system," said Glenis Willmott, rapporteur on medical devices. "So we've introduced much stricter requirements for the bodies that authorize medical devices, and will insist that particularly high risk devices, such as implants, joint replacements or insulin pumps, will be subject to additional assessments by experts before they can be authorized."

Under the measure, devicemakers would need to provide clinical evidence of device safety, especially for higher-risk devices. They can also expect random facility inspections after devices are on the market, as well as an additional safety-check for high-risk devices. In addition to a notified body, a special committee of experts would confirm that all requirements are met.

There would also be stricter controls on notified bodies, which would have to include medically skilled members.

Additionally, the measure would require stronger postmarket surveillance. For example, patients would receive an "implant card" so they and their physicians can track which product has been implanted.

"With the [breast implant] scandal, many women simply didn't know if they had received defective implants or not. So we've also introduced a Unique Device Identification (UDI) system so we know which patient has which device; this will make it much easier to trace patients if there's a problem and patients will also be given an implant card with the UDI, which they can use to access information via a publicly accessible database," Wilmott added.

In addition to the device measures, the Health Committee MEPs approved stricter data and ethics requirements for diagnostics. These would affect diagnostics used for pregnancy testing, DNA testing and other areas. The legislation would also require EU member states to inform patients of potential consequences with DNA tests.

Both reports will be up for a full House vote early next year. — April Hollis

Walgreens Officially Breaks-Up with Theranos

Walgreens is terminating its relationship with Theranos, and will no longer offer its testing services at any of its stores.

Walgreens also said it would close all 40 Theranos Wellness Centers in its Arizona stores and will be working to help transition customers.

Those actions came after Theranos rescinded test results from the past two years for its Edison blood-testing diagnostics (*IDDM*, May 20).

The pharmacy chain said that CMS rejected Theranos' correction plan, noting that looming sanctions justified ending the partnership. The firm also was hit with criminal investigations by the SEC, the U.S. Attorney's Office for the Northern District of California and U.S. Department of Justice (*IDDM*, April 22).

Walgreens further informed Theranos that tests collected at its Wellness Centers at stores in Arizona, must be sent only to Theranos' certified lab in the Phoenix area or to an accredited third-party lab for analysis.

Theranos said it was disappointed with Walgreens' decision, and it would continue to serve customers through independent retail locations in Arizona and California.

The once-prized company has yet to provide details and documentation to Walgreens, its critical source of revenue, or how its tests work and compare to standard blood tests. — Joya Patel

CDC Presses Industry For Antibody-Based Zika Diagnostic

The Centers for Disease Control and Prevention is urging industry to develop antibody-based Zika diagnostic tests.

In exchange, the agency said it prepared to offer non-exclusive license agreements to develop the tests, as well as materials, information and technology transfer.

CDC Director Tom Frieden told reporters at the National Press Club that no company has taken the agency up on its offer to develop a much-needed antibody-based test that would help to distinguish the infection from others.

He noted that CDC scientists have optimized testing for a rapid, highly sensitive test that can detect the virus in urine or blood in acutely infected individuals, and those tests have been disseminated to 100 labs around the U.S. and globally.

But more effective antibody-based diagnostics are desperately needed to determine if someone has been infected in the past. Frieden acknowledges that a non-exclusive license could pose a potential marketing barrier to manufacturers seeking to exclusively develop tests using CDC's groundwork.

He said the agency originally reached out to a diagnostic manufacturer to contract out development of Zika diagnostics, but the company's year production timeline would not address the immediate need.

The U.S. Senate and House separately passed spending bills in late May to fight the Zika virus with measures that include HHS funding for vaccines, therapies and diagnostic tests.

The Senate passed an amendment to a transportation appropriations bill that provides $150 million for an HHS emergency fund to spur the development of Zika countermeasures. A $622 million measure passed the House that would allocate $103 million for the development of preventative measures.

The FDA also has issued four emergency use authorizations, mostly for polymerase chain reaction (PCR) tests for the virus (*IDDM*, May 2).
— Joya Patel

FDA Gives Thumbs Up To Aspire Bariatrics' Obesity Device

The FDA has granted marketing approval to Aspire Bariatrics' obesity device AspireAssist System as an endoscopic alternative to weight loss surgery for people with moderate to severe obesity.

The system approaches obesity treatment through portion control using a surgically-placed tube to drain a portion of stomach contents after every meal, removing approximately 30 percent of calories consumed.

The device consists of a tube that connects the inside of the stomach to a skin-port outside of the abdomen. After eating, the patient attaches an external connector and tubing to the skin-port, opens the port valve, and drains the food before it has been absorbed by the body.

It is intended for long-term use, in conjunction with diet and exercise, counseling and medical monitoring. The device is implanted in a 15-minute outpatient procedure, is fully reversible, and does not alter the patient's internal anatomy.

The application was supported by a clinical trial in 111 patients who lost an average of 12.1 percent of their total body weight compared to 3.6 percent for the control group. Clinical trial results also show improvements in diabetes and hypertension.

The device labeling carries a long list of people who should not use the device, including those who have had abdominal surgery, a history of gastric ulcers, uncontrolled hypertension, a history of cardiovascular disease, anemia, pregnant or nursing, or eating disorders.

AspireAssist it is not intended to be used for short durations in those who are moderately overweight. It is intended to assist in weight loss in patients aged 22 and older who are obese, with a body mass index of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy. — Joya Patel

Teva Yanks Zecuity Patch from Shelves

Teva has announced the temporary suspension of marketing, distribution and sales of its Zecuity patch in the U.S. to investigate the cause of burns and scars related to its use.

The company voluntarily suspended sales of the migraine patch based on a flood of post-marketing reports dating from September 2015, linking the patch to adverse application site reactions including burns, scars, cracked skin and discoloration (IDDM, June 13).

FDA and Teva will work in partnership to determine the cause of the adverse events. Until an investigation is completed, the company is recalling all patches at the pharmacy-level and putting further sales on hold.

Teva gained rights to Zecuity along with its acquisition of NuPathe in January 2014. — Joya Patel

Australia Issues Alert for Medtronic Deep Brain Stimulation Devices

Australia's TGA and Medtronic Australasia have issued a hazard alert for five models of deep brain stimulation devices associated with potential loss of coordination in movement.

Deep brain stimulation devices are implantable, programmable devices that deliver electrical stimulation to the brain to treat the symptoms associated with movement disorders, including epilepsy and Parkinson's disease.

The hazard alert cites a case report published in the Journal of Neurosurgery in May in which a patient lost coordination in the water and was unable to swim. Implanted deep brain stimulators may put patients at risk for drowning by causing temporary impairment.

Affected models include the Activa PC, SC and RC series, and the Kinetra 7428 and Soletra 7426.

Read the hazard alert here: www.fdanews.com/06-14-16-TGAMedtronicHazardAlert.pdf. — Joya Patel

MHRA Wants Human Factors Use Data for Devices

Human factors should be incorporated into the product design throughout the product lifecycle as part of the benefit-risk profiling of a medical device or combination product, MHRA says.

The Medicines and Healthcare Regulatory Agency is advising devicemakers on what to consider when developing devices to eliminate design-related problems that contribute to unsafe or ineffective use in guidance released June 15.

The guidance maps out a comprehensive design process and steps manufacturers should take to reduce errors that could potentially lead to patient harm.

First, devices should be designed based on user need, and instructions for use should include design and development inputs with usability requirements based on intended use.

Formative studies are expected to be iterative so that information is learned from the earliest stages of development. Manufacturers are required to establish a usability engineering file as a part of device documentation to address evolving issues. Further design changes may be necessary following clinical studies.

Any changes to a product need to be evaluated, and manufacturers should consider and document additional human factor engineering studies.

Medicinal products that include a significant device component, either co-packaged with, or integral to the medicinal product, should be analyzed for risk and documented in the risk management plan.

In the case of combination products, where the device is marketed as an integral part of a single product, both the device and medicinal component will be regulated as a single product.

Any differences between the device used in pivotal clinical studies and that proposed for marketing should be clearly explained and additional human factor engineering studies may be required.

MHRA's guidance is consistent with the FDA's final guidance on human factors to be considered, that was released in February (*IDDM*, Feb. 26).

MHRA is accepting comments on the draft until Aug. 5. Read MHRA's draft here: www.fdanews.com/06-15-16-MHRAGuidanceHumanFactorsandUsability.pdf. — Joya Patel

NICE Recommends Boston Scientific Prostate Laser Treatment

Boston Scientific's GreenLight XPS Laser Therapy System has received a nod of approval from NICE to treat enlarged prostate.

The agency estimates the device could save the UK's National Health Service up to £3.2 million annually by treating an estimated 13,600 patients on an outpatient basis for benign prostatic hyperplasia (BPH) rather than the traditional surgical resection.

NICE's approval was based on comparative data collected from a 291-patient, nine-country European study comparing the system to transurethral resection of the prostate (TURP).

There were fewer initial serious post-procedure complications and lower hospital readmissions with the GreenLight XPS, and outcomes were as effective as the current standard surgical treatment.

The guidance notes that there's currently not enough evidence to support the use of the device in high-risk patients, recommending specialists collect information on outcomes if the device is used in this subset of patients. It also recommends that where GreenLight XPS is used, urology services should be redesigned to ensure day-case surgery is available.

Boston Scientific inherited GreenLight XPS system when it acquired American Medical Systems' urology portfolio from Endo. The FDA-cleared system is designed to increase the power and area of a laser beam by 50 percnet and offer a wider tissue vaporization effect with consistent vaporization and coagulation.

Read NICE's device guidance here: www.fdanews.com/06-17-16-NICEGreenLighXPS.pdf. — Joya Patel

BRIEFS

Japan Approves Elekta's Icon

Elekta's Leksell Gamma Knife Icon has been cleared for clinical use by both the Japanese Ministry of Health, Labor and Welfare and the Nuclear Regulatory Commission in the United States.

Icon is used in radiosurgery for brain tumors and vascular malformations. The device uses integrated stereotactic cone-beam CT (CBCT) imaging technology that monitors cranial position using infrared marker tracking. The system can check a patient's position against the treatment plan and automatically recalculate the plan to correct for movement.

The product received 510(k) clearance from the FDA in August 2015.

Nasolacrimal Compression Device Class I

The FDA is classifying the nasolacrimal compression device as Class I, effective June 10.

This classification was based off of Innovatex's request for Class I designation for its Tear Duct Occluder (originally referred to as the Glaucoma Companion Nasolacrimal Compression Device) on June 27, 2014.

A nasolacrimal compression device is a prescription device that is fitted to apply mechanical pressure to the nasal aspect of the orbital rim to reduce outflow through the nasolacrimal ducts.

Read the final order here: www.fdanews.com/06-14-16-NasolacrimalCompressionDeviceClassification.pdf.

MHRA Update on QRISK 2 Investigation

MHRA issued an update on errors associated with the TPP QRISK 2 Calculator, which detects the potential risk of cardiovascular disease.

The MHRA initiated an investigation following reports of inaccurate results of the calculator that runs on the UK-based company's SystmOne clinical software. The agency notes that the issues pose little risk to patients.

Doctors are advised to identify patients with incorrect scores in need of reassessment, and to explore different avenues to minimize the risk of heart disease, if necessary.

Read MHRA's update here: www.fdanews.com/06-14-16-MHRAWarningQrisk2.pdf.

Oventus Releases 3D-Printed O_2Vent

Australian medical device company Oventus Medical will unveil its flagship medical device, the O_2Vent, for the treatment of snoring and sleep apnea in the U.S.

The 3D-printed O2Vent is custom-fitted to a patient's mouth and directs air to the back of the mouth. It is an alternative treatment to continuous positive airway pressure (CPAP) treatment.

A recent study showed snoring was eliminated in 82 percent of patients along with improved oxygen levels during sleep.

In March 2016, the device received 510k clearance in the U.S. and is expected to be available later this year.

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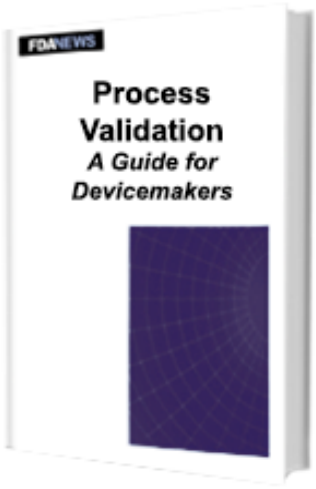

Process Validation
A Guide for Devicemakers

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.

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