INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Indian Bill Would Formalize Regulation of Medical Devices

The Indian government is laying the groundwork for a complete overhaul of the country's medical device regulations. The first step is an amendment that would define medical devices as a distinct product sector under the 65-year-old drugs and cosmetics law.

The proposed language defines a medical device as any instrument, implant or other article used to diagnose or treat a disease, replace or support a physiological process, support or sustain life, control contraception via IVD or apparatus, or disinfect other medical devices. Software is explicitly included, as are devices meant for use in animals.

However, notes Vince Suneja, CEO of TwoFour Insight Group, the proposal makes few other practical changes. It formalizes a requirement for an independent panel to advise the Central Drugs Standard Control Organization, but one has already been meeting.

The proposal also does not explain how device regulations will be enforced or how medical technologies will be approved for market, he says. If the amendment passes, the government will need to make decisions about how to regulate the sector, Suneja says. Issues to be confronted before comprehensive device regulations can be established include how closely to hew to international standards and whether a centralized licensing scheme is appropriate.

Clinical Trial Changes

The measure also carries new penalties for clinical trial wrongdoings. Investigators conducting trials of new medical products in India would face up to five years in jail for trial violations if lawmakers approve the bill.

It's ambiguous whether the punishments would apply to devices, says attorney Mark Barnes, partner, Ropes & Gray, but he believes that is the government's intent. He expects that any further guidance on the issue will more explicitly incorporate devices.

Punishments would vary based on the offense, with sentences of up to three years for investigators who conduct trials without

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government permission, according to the draft legislation, which was released Dec. 31 by the Department of Health and Family Welfare. Repeat offenders could face five years in prison and thousands of dollars in fines.

Investigators also could face up to a year in prison for not compensating a clinical trial participant or family member for an injury or death. India recently finalized a formula for determining trial compensations.

The addition of jail time for violations represents a drastic shift from current punishments, which include prohibiting an investigator from performing trials in the country, Barnes says. He fears sponsors will have a hard time getting high-quality investigators to conduct trials in India because of the threat of possible imprisonment.

Barnes says the complexity and ambiguity of India's clinical trial regulations also make it hard to know what types of transgressions might warrant jail time. If a patient shows up late for a scheduled review, that could be a violation of protocol and subject to potential penalty, he says.

The draft bill, which will be introduced when Parliament reconvenes in February, replaces a 2013 version with minimal changes to other provisions. This is the third effort to amend the Drugs and Cosmetics Act after prior attempts stalled in 2007 and 2013. But Barnes and Suneja expect a strong push for the bill to pass this session due to backing from Prime Minister Narenda Modi's government and new regulations encouraging foreign investment in device companies (*IDDM*, Jan. 5).

This move "at the highest level, recognizes that devices are different from drugs," says Suneja.

Comments on the Drug and Cosmetics (Amendment) Bill, 2015 may be submitted to anita.tripathi76@nic.in through Jan. 12. View it at www.fdanews.com/01-05-15-IndiaBill.pdf.
— Robert King, Elizabeth Orr

Silverman Leaving FDA; Oversaw Major Restructure of CDRH Compliance Office

CDRH Office of Compliance Director Steve Silverman told senior staff Monday that he will leave the FDA next month to pursue opportunities outside the government. His last day at the agency will be Jan. 16, according to an internal memo provided to *IDDM*.

Jan Welch, deputy director for regulatory affairs in the Office of Compliance, will serve as acting OC director until a permanent replacement is found, the memo says. Silverman did not return a request for further details of his plans by press time.

As head of OC, Silverman oversaw a major reorganization that morphed the office from four divisions to five — analysis and program operations, manufacturing and quality, premarket and labeling compliance, international compliance operations and bioresearch monitoring — and focused limited resources on encouraging quality rather than on enforcement.

The overhaul also fueled two pilot programs designed to increase inspection efficiencies. Under one program, OC will conduct targeted inspections of companies that make implantable battery-driven devices. A second pilot on voluntary compliance improvement allows devicemakers with minor quality concerns a two-year break from FDA surveillance to define and resolve the problems with the aid of outside consultants.
— Meg Bryant

Industry to TGA: More Regulatory Harmonization, Less Red Tape

Australian authorities could speed up the path to market for innovative devices by accepting more international conformity assessments and global standards, an industry group says.

The Medical Technology Association of Australia's comments, submitted to an expert panel reviewing the country's device regulations, also

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urges regulators to accept premarket assessments completed by recognized foreign entities.

The Therapeutic Goods Administration has accepted European authorizations for most devices since 2002, but still requires its own review for most class II devices, as well as for combination products and devices containing materials of animal, microbial or recombinant origin, MTAA notes. These products were assessed "to predominantly the same requirements and standards in Europe by qualified and internationally recognized assessment bodies, unlike the TGA [which is] not accredited by a recognized accreditation body to conduct such assessments," the group says.

In particular, MTAA says the TGA should work with European designating authorities to assess specific notified bodies whose work could be accepted. Alternatively, the agency could look to International Medical Device Regulators Forum documents to help it develop a list of recognized notified bodies, the group says, adding that the TGA lacks the resources and experience to perform its own notified body assessments.

TGA Lags in Use of Global Standards

The group also wants the TGA to accept more international standards, saying this would improve confidence in approvals by foreign authorities. According to MTAA, Australia recognizes only 44 such standards — far fewer than other founding members of the Global Harmonization Task Force, which preceded IMDRF. By contrast, the U.S. recognizes 261; Europe, 222; Canada, 181; and Japan, 104.

Other reforms industry is seeking include:

- A rewrite of Australia's combination product regulations to take the risk level of both components into account. That way, if a low-risk medicine is applied to a low-risk device, the overall product would be considered low-risk. Currently, all combo products are deemed high-risk and subject to a stricter assessment process even if each component alone is classified as low-risk;
- Alignment of the TGA's device classifications with global definitions. MTAA points out that a decision to put both total and partial joint replacements in Class III has caused confusion because it doesn't match the EU definition, which places partial joint replacements in a different class; and
- Limiting assessments of devices previously approved by recognized authorities to new indications for use and other notable differences.

Accelerated Review

The expert panel sought input on whether Australia needs an accelerated review program. Industry says the TGA should fix what is creating delays in the normal approval process rather than introduce a separate accelerated approval program.

The group also expressed concerns about the potential cost of such a program.

Finally, the group says the TGA should eliminate the requirement that Class I devices be listed on the Australian Register of Therapeutic Goods. Currently, there is no review process before a Class I device can be listed with the TGA, and the fee for listing is only about US $65 per year. But that means that there's little incentive for manufacturers to remove out-of-date entries from the database, MTAA says.

Further, listing Class I devices on the public register gives the perception that they have been approved or cleared for use by the TGA, which is not the case, the group says. While opposing the listing of Class I products, MTAA says they should still be subject to other regulatory requirements, such as postmarket monitoring and recalls.

View MTAA's comments at www.fdanews.com/01-12-15-MTAA.pdf. — Elizabeth Orr

Human Factors, LDT Guidance On CDRH's Radar for 2015

CDRH said Thursday that it will finalize guidance this year on human factors engineering, device reprocessing and adverse event reporting for laboratory-developed tests.

MDUFA III requires the device center to publish a list of guidance documents that it expects to complete each year. This year's list includes 20 priority documents — 12 final and eight draft — plus seven "B-list" draft guidance documents to be developed as resources allow. CDRH also plans to revisit guidance issued in 1985, 1995 and 2005 as part of an ongoing retrospective review.

Other topics in the queue for final guidance this year:

- 510(k) submissions for medical devices that include microbial agents;
- Balancing premarket and postmarket data collection for PMA devices;
- Expediting PMAs on devices meant to fill an unmet need or treat a life-threatening or irreversible disease; and
- Clinical and nonclinical studies of coronary drug eluting stents.

The center plans to develop draft guidance on general wellness products, medical device accessories, medical device decision support software, benefit-risk factors for IDE submissions, unique device identifier direct marking, informed consent for observational data and adaptive design for clinical studies as well as a draft UDI FAQ.

Lower down on the priority list are a technical guide on 3D printing and draft documents on the use of symbols in labeling, direct-to-consumer genetic testing and device interoperability.

In a Wednesday *Federal Register* notice announcing the list, the FDA seeks feedback on the regulation of patient-matched instruments for orthopedics and devices meant for aesthetic use. In the case of patient-specific joint replacements created from imaging scans, the agency wants input on ways to ensure that the design process functions as intended and on the critical

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2015 Guidance, *from Page 4*

parameters necessary to create an effective preoperative plan. The agency also wants suggestions on how to monitor the results of the implant if the manufacturer doesn't control the design system.

In addition, the FDA is seeking comments on clinically meaningful tools to evaluate the effectiveness of aesthetic-enhancement devices, including how gender and ethnicity-specific tools could be developed and whether patient-reported outcomes should be considered valid.

View the list of planned guidances at www.fdanews.com/01-12-15-FDA2015guidance.pdf. — Elizabeth Orr

FDA LDT Public Meeting Kicks Off: Divisions Drawn Along Expected Lines

The FDA's proposal to regulate laboratory-developed tests came in for heavy criticism at a two-day public hearing Thursday and Friday, with presenters lining up to denounce the FDA's proposal. While some speakers expressed support for the FDA's proposals, they were outnumbered out by the voices of LDT manufacturers and physicians who feared FDA regulation would hurt patient care and discourage innovation.

Mari Savickis, American Medical Association, referred to the FDA's proposal as "unworkable, dangerous, and undermining the public health." If the proposal is put into place as written, many labs will stop performing LDTs for rare diseases because the expense of garnering FDA approval will be so high, she said.

The FDA proposal would phase in FDA regulation of LDTs over nine years, beginning two years after a final guidance is issued requiring FDA clearance for the tests deemed the most high-risk. The proposal exempts several categories of LDTs from premarket authorization, including tests for rare diseases and so-called "traditional LDTs" that are performed in a single hospital or health care system. But the definitions for those exempt tests caused significant pushback.

Arthur Hagar of the Georgia Public Health Laboratory says the FDA proposal's exemption for tests for rare diseases was inadequate because it was based on the number of tests performed not the number of cases of a disease. For example, as written, the FDA proposal would seem to require FDA approval for screening tests used on newborns. If FDA regulatory demands drive up testing costs, the state might not be able to pay for testing of poor infants, he says.

Grace Kubin of the Texas Department of State Health Services says public health labs used LDTs to quickly detect and respond to emerging infectious diseases. "We're constantly responding to the next new disease and need flexibility to quickly develop tests," she said. "The 510(k) and PMA paradigm does not translate to an effective scheme."

Regulation Too Costly

"The FDA has to understand that our members lack the resources to prepare regulatory submissions," says Roger Klein, chair of the professional relations committee at the Association for Molecular Pathology. "And even if we could, the cost wouldn't be justified by the benefit to patients."

Like Klein and others, Gibbs urged the FDA not to regulate tests ordered by physicians and performed by pathologists. The "traditional LDTs" exemption as now written ignores medical advances and would apply only to tests following standards set almost four decades ago, he said.

Panelists also disagreed as to what exactly made a test an LDT, including questions as to whether they could include software components. Risk categories have historically been difficult to define, said Curtis Hanson, Mayo Clinic, who shared an anecdote about his hospital's experience in classifying the tests. "We could never

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come up with a definition of low, medium, or high-risk tests," he said. "Should it be based on whether people understand the test, whether papers about it have been published, or whether proficiency testing is available for the people performing the test?"

However, Andy Fish, president of AdvaMed Dx, said a first step could be convening advisory panels to discuss tests in the context of the specific disease area. He noted his group has developed proposed risk classifications for diagnostics, which could be expanded to cover LDTs. AdvaMed Dx supports FDA regulation of LDTs.

Patient Groups Support FDA

Some representatives from patient groups said they thought FDA regulation of LDTs could be an important safety step. Laura Koontz of the Ovarian Cancer National Alliance recounted the history of the OvaSure test — an LDT marketed for the detection of ovarian cancer that led to hundreds of unneeded hysterectomies before being recalled in 2008.

"This guidance would go a long way toward assuring Ovasure doesn't happen again," she said. "It would require premarket review, and the adverse event reporting would allow bad tests to be caught quickly."

In wrapping up the meeting, CDRH director Jeffrey Shuren said the agency could take into consideration the feedback it has received in reworking the LDT draft.

Next Step: Clarification

"It was apparent a lot of details have left people confused," attorney Jeffrey Gibbs, partner, Hyman, Phelps & McNamara, said, including how the FDA will define rare diseases and how it defines a healthcare system.

Gibbs expects the FDA to rework the definition of a rare disease in response to comments, though how it will do so is an open question. Currently, it would apply to a test performed 4,000 or fewer times per year; what's unclear, he tells *IDDM*, is whether the FDA will instead use the standard of 200,000 tests per year set in the Orphan Drugs Act, or whether it will apply the exemption to tests for conditions diagnosed 4,000 times per year.

He believes the FDA should issue a revised draft and go through a second comment period to check any changes it makes in response to this round of comments.

Comments can be submitted on the FDA's proposed regulatory framework until Feb. 2.
— Elizabeth Orr

Cerus Wins Extra Year of Patent Protection for Intercept System

The U.S. Patent and Trademark Office has extended for one year the patent on a novel device that reduces pathogens in blood platelets and plasma while the FDA reviews its use in treating Ebola patients.

Cerus' Intercept blood system received FDA approval in December. It is now being tested as a way to treat plasma from Ebola survivors before it is transfused into patients fighting the disease. Transfusing Ebola patients with blood from survivors has been shown to be an effective treatment, and Intercept would help to ensure that the plasma they receive is free of common bacteria, viruses and parasites.

The FDA granted an IDE for the Ebola trial in November.

In a Jan. 5 *Federal Register* notice, the Patent Office notes that patents may extended for up to five years if the product has been subject to regulatory review and for one-year periods if the review will extend beyond the expiration date of the patent. Cerus filed its request for a one-year extension on Dec. 5 while the FDA was still reviewing its modular PMA for the Intercept

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system. The last component of the PMA was submitted on Nov. 29, 2013.

The patent was set to expire on Jan. 15.

Separately, the Concord, Calif., devicemaker announced that Intercept met its primary endpoint of red blood cell viability in a European Phase 3 study involving cardiovascular surgery patients. The randomized, double-blink, controlled, multicenter clinical trial found that red blood cells treated by Intercept were of the same quality and mean hemoglobin content as control RBCs.

View the *Federal Register* notice at www.fdanews.com/01-12-15-intercept.pdf. — Elizabeth Orr

Guidance Creates Two-Step Process For Patent Subject Matter Eligibility

Interim guidance from the U.S. Patent & Trademark Office on patent subject matter eligibility clarifies how the agency will review patent applications in the wake of the Supreme Court's decisions in *Association of Molecular Genetics v. Myriad* and *Mayo v. Prometheus*.

In both cases, the high court ruled that genes and natural processes generally are not patent-eligible unless they meet very specific criteria. In a third case, *Alice Corporation Pty. Ltd. v. CLS Bank International et. al.*, the justices said patents could not be issued on overly abstract concepts.

Putting the court's decisions into practice has proven difficult, however, as patent examiners have brought differing interpretations of those opinions to their job, says D'Vorah Graeser, CEO of Graeser Associates International. "The guidance is really needed so there will be consistency in examination," she tells *IDDM*.

Graeser says the guidance should be especially helpful to devicemakers because it clarifies how software patent applications will be evaluated.

The guidance, largely overlooked in the holiday hoopla, creates a two-step flow chart for evaluating patent subject matter eligibility. Examiners must first ask whether the patent is for "a process, machine, manufacture or composition of matter." If the answer is no, the claim is not eligible for a patent. If the answer is yes, the examiner must then ask whether the claim is directed to "a law of nature, natural phenomenon or an abstract idea." If that answer is yes, the claim is considered eligible only if the claim includes further elements that "amount to significantly more than the judicial exception," the guidance says.

The Supreme Court's definition of "significantly more" covers improvements to another technology or technical field, improvements to the functioning of the computer itself, reducing or transforming matter into a different state or thing, adding a step beyond those routine in the field, or "other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment." The additional elements should be considered individually and in combination, USPTO says.

'Significantly More' Clarified

The guidance also clarifies elements that would *not* qualify as "significantly more." These include adding the words "apply it" or an equivalent, explaining activities already well-known to the industry, adding an insignificant extra solution activity such as extra data gathering, or linking the "apply it" exception to a particular environment or field of use.

The guidance includes specific examples of allowable and unallowable claims relating to methods of treatment, purified proteins, genetically modified bacteria, mixtures of bacteria, nucleic acids, antibodies and cells. For example, a bacterium engineered to have two different hydrocarbons (as opposed to the natural occurring single hydrocarbon) would be patent-eligible, while a human gene would not, the guidance states.

Comments are due to PTO-P-2014-0058 by March 15. View the interim guidance at www.fdanews.com/01-12-15-patent-eligibility.pdf. — Elizabeth Orr

IMDRF Finalizes Procedural Docs On SOPs, Terms of Reference

The International Medical Device Regulators Forum kicked off the new year by releasing final documents on terms of reference and standard operating procedures.

The SOP document describes the composition and operation of IMDRF's management committee and work groups and details the stages of document development — from identifying work items to proposing and finalizing harmonized guidance. The SOP also introduces a coding system for designating the status of a document.

An inventory of documents and actual texts will be maintained by the IMDRF secretariat, which will rotate among the founding regulatory authorities. The inventory will note the stage of development of each document, the SOP says. A searchable database of all final and proposed documents will also be maintained on IMDRF's website.

IMDRF documents will be updated on an as-needed basis. Guidance developed by the Global Harmonization Task Force and available via a repository on IMDRF's website will not be routinely updated, the SOP says.

The IMDRF Terms of Reference document spells out the group's mission, goals, objectives and scope, as well as its governance structure and work product-related activities. It includes an organizational chart for management level (decisionmaking, strategic direction, work plan monitoring) and operational level (technical document development) efforts.

View the SOP document at www.fdanews.com/01-12-15-imdrf-sop.pdf. The Terms of Reference document is at www.fdanews.com/01-12-15-imdrf-tor.pdf. — Meg Bryant

Mexico Deregulates 100s of Low-Risk Devices, While Colombia Adds Some

Mexico's regulatory body, COFEPRIS, has deregulated an additional 573 low-risk medical devices, including diagnostic agents, hygiene products and dental treatment materials and supplies, bringing to 2,242 the total number of products sprung from registration over the past few years.

According to a notice in the Dec. 22 *Official Journal*, the safety and efficacy of the products, which also include prosthetics, orthotics and surgical material, is well established and supported by technical and scientific information.

A regulatory reform policy published in December 2011 deregulated 1,669 other products.

Elsewhere in Latin America, Colombia's INVIMA added 10 categories of products to the list of medical devices that require registration. Included are calf and thigh orthotics, rib and clavicle immobilizers, elbow supports, abdominal girdles and posture correction products.

Read the COFEPRIS agreement in Spanish at www.fdanews.com/01-15-Mexico-COFEPRIS.pdf. The INVIMA notice is in Spanish at www.fdanews.com/01-15-Colombia-INVIMA.pdf. — Jonathon Shacat

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– Nicola Martin, Associate Director, Quality & Compliance, Covidien

"Very pleased that most speakers were directly from industry, either FDA or corporations. Good to hear directly from the source."

– Rossellen Miller, Product Development Quality Engineer, Terumo Cardiovascular

"Subject matter was very relevant. Interaction with attendees was great."

– Michael Healy, QA/QC Director, Tryton Medical

Now in its 12th year, FDAnews' **Medical Device Quality Congress (MDQC)** has become the indisputable must-attend annual quality and compliance event for medical device and diagnostics professionals. **With over 1,700 attendees since 2004, there's simply no other medical device quality event that even comes close.**

Invited FDA Speakers

- Melinda Plaisier, Associate Commissioner for Regulatory Affairs, Global Regulatory Operations and Policy, ORA, FDA
- Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA
- Ronny Brown, Chief, Recall Branch, Division of Risk Management Operations, OC, CDRH, FDA
- Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA
- Dr. Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA
- William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA
- Dr. Joni Foy, Deputy Director, Office of Device Evaluation, CDRH, FDA
- Dr. Suzanne Schwartz, Director, Emergency Preparedness/Operations and Medical Countermeasures, OCD, CDRH, FDA
- Phil Pontikos, CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH

Industry Experts

- Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations (MDQC Co-chair)
- Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA (MDQC Co-chair)
- Karl Vahey, Director of Compliance, International RA/QA, Covidien
- Larry Kopyta, Vice President, Quality Assurance & Regulatory Affairs, Omnyx
- Patrick Caines, Director, Product Surveillance, GE Healthcare
- Paul Brooks, Vice President and Country Manager, BSI Americas
- Vinny Sastri, President, WINOVIA
- Steven Walfish, President, Statistical Outsourcing Services
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PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 17

8:30 a.m. – 9:00 a.m.
REGISTRATION AND CONTINENTAL BREAKFAST

9:00 a.m. – 12:00 p.m.

Integrating Risk Management Into Complaint Management And CAPA Processes

The importance of integrating risk management into your processes can't be overstated, and more and more devicemakers are seeing that its effective application helps them better prioritize and focus on their most important concerns – especially with CAPA and complaint management. With complaints on the rise (thanks to social media) and the FDA's high expectations of your CAPA program, embracing the tenets of risk management to improve your processes is a no-brainer. Attend this in-depth session – taught by a risk management expert who deals with complaint management and CAPA every day – and you'll return to your office filled with newly-acquired knowledge and ready to move into a leadership role in this always difficult area.

Attendees will learn:

- Understanding how to review complaints and CAPAs with a risk management mindset to prioritize valuable time and resources
- Creating and writing SOPs that govern and explain how you integrate risk management to manage complaints and CAPAs — the FDA will expect to see these during an inspection
- Managing emerging sources of complaints and applying risk management tools to determine how best to handle them

Larry Kopyta
Vice President, Quality Assurance & Regulatory Affairs, Omnyx

CONFERENCE AGENDA

Tuesday, March 17

12:00 p.m. – 1:00 p.m. | REGISTRATION

1:00 p.m. – 1:15 p.m.

Welcome and Introduction by Co-chair Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations

1:15 p.m. – 2:00 p.m.

FDA Update On Inspectional Corps Re-Organization — What Does it Mean For Devicemakers?

The FDA unveiled a broad plan that will change the way it inspects devicemakers, handles recalls, issues and reviews enforcement decisions and screens imports, with companies likely to start feeling the impact in 2015. The reorganization will create a distinct inspectorate for just medical devices, eliminating the existing region-based model. In an eight-page document, CDRH outlined the steps it will take to create a new specialized approach to inspections. The plan includes creating specialist investigators who will be extensively trained in specific types of devices. CDRH says it will survey staff to subdivide its inspectorate into subspecialties.

Attendees will learn:

- Why Commissioner Hamberg asked for feedback on how to improve operations
- What's the latest on the specialization and training that investigators are receiving

Melinda Plaisier, Associate Commissioner for Regulatory Affairs, Global Regulatory Operations and Policy, ORA, FDA (invited)

2:00 p.m. – 3:30 p.m.

FDA Expectations For Risk Management Files And Their Relationship To ISO 14971 Requirements

Many devicemakers are relying on FMEAs to be the heart of their risk management strategy. But if that's your strategy, you're looking for trouble. For starters, a FMEA is not compliant with ISO 14971, and FDA and international regulators want to see comprehensive risk management that covers and fully documents all the known risks of your product. So, what exactly are the expectations for using risk management files in production and post-production to make smart risk-based decisions? This panel discussion will feature FDA and industry representatives who will explore best practices in using FMEA and ISO 14971 properly — and show you how to avoid the trap of overreacting to every risk that might present itself.

Attendees will learn:

- How FDA views using FMEA, ISO 14971 to remain proactive within your risk management strategy
- What do regulators want to see when they examine risk management files? Is there a sweet spot between too little information and too much?
- Best practices for creating holistic event tracking methods that provide more accurate views of a product's risk profile
- What companies need to do to address the latest in ISO 14971 enforcement — including how devicemakers are struggling with EU compliance

Moderator:
Vinny Sastri, President, WINOVIA

Featured FDA Panelists:

- **William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA**
- **Dr. Joni Foy, Deputy Director, Office of Device Evaluation, CDRH, FDA (invited)**

Panelists:

- **Karl Vahey, Senior Director Global Quality and Compliance, Covidien**
- **Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations**
- **Paul Brooks, Senior Vice President, Healthcare Solutions, BSI Group**

3:30 p.m. – 3:45 p.m. | REFRESHMENT BREAK

3:45 p.m. – 5:00 p.m.

Effective Management of Front And Back Inspection Rooms — Secrets You've Never Heard and Answers To Questions You've Always Wanted To Ask

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. Plus add the FDA's newest push to develop teams of highly qualified investigators with a deep knowledge of your device. Together, you're in for some really tough inspections. Worried? Don't be. This panel will provide you pages of great tips and tricks to designing, staffing and managing your inspectional war rooms. Our experts will also answer those questions that have been nagging at you for years. Don't miss this exciting panel!

Attendees will learn:

- Polite in the front, craziness in the back? It doesn't have to be. Understanding the synergy of the front and back rooms
- Handling data requests, particularly for electronic records — best practices from inspectional veterans
- Being a SME in your job doesn't make you an

inspection SME. Tips for staffing your war rooms with the appropriate people to interact with the FDA

Moderator:
Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA

Featured FDA Panelists:
- **William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA**
- **Phil Pontikos, CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH (invited)**

Panelist:
- **Larry Kopyta, Vice President, Quality Assurance & Regulatory Affairs, Omnyx**

5:00 p.m. – 6:30 p.m. | NETWORKING RECEPTION

Wednesday, March 18

8:30 a.m. – 9:00 a.m. | CONTINENTAL BREAKFAST

9:00 a.m. – 9:15 a.m.

Welcome and Introduction by Co-chair Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA

9:15 a.m. – 10:00 a.m.

Medical Device Single Audit Program Gaining Steam, Canada To Require Audits in 2016

All signs point to progress with the Medical Device Single Audit Pilot Program, in which a third-party inspector's single audit is considered sufficient to prove compliance in the U.S., Canada, Australia and Brazil. Results to date also suggest that a single audit costs less and takes less time than is required in each separate market. In the meantime, Canada is taking a leadership role, announcing that beginning in 2016, products sold there will require shared audits. Plan to attend this session to learn more about this breakthrough pilot and how it could dramatically affect your business.

Attendees will learn:
- How multiple sites will be audited under the program
- Results from results, including comments from both companies and inspectors
- Could EU nation states join the program in 2015?

Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA (invited)

10:00 a.m. – 10:45 a.m.

Recalls: Communicating With FDA — What are the Regulatory Requirements and Expectations?

Getting devices off the market that pose a risk to patients is always your first priority. But effectively communicating with the FDA about it is a close second. In this presentation, the chief of the Recall Branch of CDRH will guide attendees though current recall policy. Plus, provide best practices for how to effectively communicate with the FDA. This session will give you a first-hand account of what the FDA expects of you.

Attendees will learn:
- Dos and don'ts when communicating with the District or the Center regarding recalls
- Understanding the 4 points that should be included in recall communications
- Tips for avoiding promotional messages within your recall announcements
- Best practices for following up with those that fail to respond to an initial communication

Ronny Brown, Chief, Recall Branch, Division of Risk Management Operations, OC, CDRH, FDA

10:45 a.m. – 11:00 a.m. | REFRESHMENT BREAK

11:00 a.m. – 12:00 p.m.

Classification and Conformity Assessment Routes For Obtaining CE Marketing and European Distribution

In order to receive a CE marking, you must travel a tortuous path of compliance with myriad regulations, most notably Directive 93/42/EEC … receive a thorough review of your device and its supporting documentation … pass an assessment of your quality systems and technical documentation … and possibly meet "state-specific" registration requirements relating to the language of the device's accompanying information. This session will start you on the right path if you desire European distribution of your devices.

Attendees will learn:
- How to properly review Directive 93/42/EEC and assure you're classifying your device correctly — failure to do so causes nothing but wasted time and money
- Best practices for working with Notified Bodies and getting their stamp of approval
- Which states have requirements regarding state-level registration and how to effectively comply
- Why some states require additional language requirements before marketing can begin

Paul Brooks, Vice President, BSI Healthcare Solutions

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 1:45 p.m.

FDA's Focus on Risk Management and Cybersecurity for Devices that Contain Software

Software has increasingly become a critical part of medical devices. More and more medical devices have software embedded or interface with another device or healthcare system that has software as an integral part. Given the increased complexity of medical device software, best practices in risk management and cybersecurity is critical and challenging.

Attendees will learn:
- What are FDA's latest initiatives on device software risk management and cybersecurity
- How a device manufacturer overcomes technical as well as regulatory compliance challenges
- What are the resources and tools available
- What are the industry's best practices

Dr. Suzanne Schwartz, Director, Emergency Preparedness/Operations and Medical Countermeasures, OCD, CDRH, FDA

1:45 p.m. – 2:30 p.m.

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 requirements: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. Also, your sample sizes must be appropriate for the type of testing you're doing and the type of product. 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. This presentation will help you select the right statistical methods to make this determination. You'll learn how to get the right sample size to ensure that user requirements are met in the product design. Finally, you'll understand how to put together a statistical methods program for design verification and validation that will satisfy FDA auditors.

Attendees will learn:
- How to examine the discrete or continuous statistical data you collect. With testing involving discrete data, you'll be doing simple pass/fail tests. With continuous data, you'll measure the output of a device, such as cycle times, voltages or pressures
- Determine how many units you must test to provide sufficient confidence that zero failures in the sample can be interpreted to mean that the product meets the user requirements, including safety factors
- Tips and tricks to look at variability, including variation from unit to unit or from batch to batch, as well as variation in their measurement systems
- Best practices for choosing design verification and validation tests, particularly regarding choice of sample size

ice Supplier Quality Management Training

- Fully understand the requirements for statistical techniques, including how different techniques can affect the design control process

Steven Walfish, President, Statistical Outsourcing Services

2:30 p.m. – 2:45 p.m. | REFRESHMENT BREAK

2:45 p.m. – 4:15 p.m.

The eMDR Challenge — Test Your Adverse Event Reporting and Implementation Expertise

Pop quiz: eMDR is an incredibly useful tool to help your company more effectively handle complaints…or eMDR is a technical nightmare that will tax your team and leave you vulnerable to new regulatory review? The answer is up to you. Mishandled, eMDR implementation can take too much of your organization's time and resources. But if you've got a smart plan in place, it can be one of your front line defenses against serious complaint system weaknesses. In this session, you'll learn from leading experts how to get it right, what your options are for implementing, and what the FDA is looking for in your MDR reporting system.

Attendees will learn:

- Requirements for MDRs on events occurring outside the US
- Reporting requirements when no injury has occurred
- Number of reports to file when there are multiple occurrences
- What to do in "User Error" situations

Moderator:

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations

Panelists:

- **Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA (invited)**
- **Dr. Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA (invited)**
- **Patrick Caines, Director, Product Surveillance, GE Healthcare**
- **Deb Kacera, Regulatory and Industry Strategist, Pilgrim Software**

4:15 p.m. – 4:30 p.m.

Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

SPECIAL FULL DAY SESSION!

DEVICE SUPPLIER QUALITY MANAGEMENT TRAINING

Thursday, March 19, 2015

In 2014, supplier management and purchasing controls rose to the #3 position within FDA enforcement statistics. The FDA's Division of International Compliance Operations, within CDRH's Office of Compliance, has been laser focused on reducing international supply chain concerns. Domestic — and overseas — inspections are also ramping up amid mushrooming international component sourcing and overseas contract manufacturing. This special full day training session is a must-attend.

BONUS: Attendees will receive copies of implementation tools; including a process map, sample questionnaire, reevaluation form, audit checklist and more.

8:00 a.m. – 8:30 a.m. | CONTINENTAL BREAKFAST

8:30 a.m. – 5:30 p.m.

Device Supplier Qualification and Management — Practical Approaches to Cost-Effective Implementation

The development of extended supply chains raises major issues in risk management. While regulators are looking more closely at device supplier management issues, companies are recognizing the value of risk management in meeting the regulatory requirements.

In addition, risk management can help device manufacturers protect themselves against problems, develop more effective management systems and control costs. You can start to prepare by focusing on these important GHTF guidance documents:

- Control of Suppliers (GHTF/SG3/N17:2008), Control of Products and Services from Suppliers (SG3/N17/2008)
- Risk Management Principles in a QMS (GHTF/SG3/N15R8)
- Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010

These guidance documents provide the foundation, but lack practical details. This workshop gives you the tools and methods you need for a cost effective implementation.

Attendees will learn:

- The supplier management process and the major steps involved
- The issues of supplier risk management — product risk, business risk, and recalls & liability risk
- How to conduct an on-site supplier audit applying risk management
- How to qualify suppliers that are virtual companies
- Understanding business issues in the supply chain and their risk challenges
- Medical device corrections & removals (recalls)
- How to select and apply supplier metrics and their role in the QMS
- Dealing with FDA record-keeping issues — sponsor vs. supplier

5:30 p.m. | TRAINING ADJOURNMENT

Expert Instructors:

John Avellanet,
Managing Director & Principal, Cerulean Associates

Dan O'Leary,
President, Ombu Enterprises

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12TH ANNUAL

MEDICAL DEVICE QUALITY CONGRESS

with Device Supplier Quality Management Training

WHAT YOUR COLLEAGUES HAVE TO SAY

"The speakers, topics and content continue to make this conference one of the best for medical device industry professionals. This is the one conference you'll want to keep in your budget."

– Paul Arrendell, Vice President, Global Quality Systems, Wright Medical Technology, Inc.

"I believe that attending this conference was well worth the time expenditure. Great participation, knowledgeable and articulate speakers. I will make this annual offering a must!"

– Karen Kirby Compliance Manager, Baxter Healthcare

"It was great to have such knowledgeable personnel available for three days to ask questions and have discussions."

– Diane Adinolfo, QA Project Compliance Manager, DEKA Research and Development

WHO SHOULD ATTEND

- Quality Assurance/Quality Control
- Manufacturing and Contracting
- Design Control
- Supply Chain Management
- Risk Management and Product Lifecycle Management
- Post Market Surveillance
- Executive Management
- Regulatory Affairs
- Research and Development
- Compliance Officers
- Consultants/Service Providers

ABOUT THE CONFERENCE CO-CHAIRS

STEVEN NIEDELMAN serves as Lead Quality Systems and Compliance Consultant to the FDA & Life Sciences practice team at King & Spalding, specializing in regulatory, enforcement and policy matters involving industries regulated by the FDA. Mr. Niedelman retired from the Food and Drug Administration in 2006 after a 34-year distinguished career, where he served as the Deputy Associate Commissioner for Regulatory Affairs and as Chief Operating Officer of the Office of Regulatory Affairs.

ELAINE MESSA is the President of the Medical Device Practice, NSF Health Sciences. She has more than 30 years of experience in FDA regulation of medical devices, having focused on the development and implementation of compliant Quality Systems for medical devices in the United States. Her most recent position was as the FDA's Director of the Los Angeles District, which is the district responsible for the largest import operations and medical device workload in the U.S. In total, Ms. Messa spent nearly 16 years in management positions within FDA district offices.

12TH ANNUAL

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☑ **YES!** I want to attend **12th Annual Medical Device Quality Congress** on March 17-19, 2015 at Bethesda North Marriott Hotel & Conference Center.

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	Early Bird Fee through Feb. 6, 2015	No. of Attendees	Regular Fee After Feb. 6, 2015	No. of Attendees
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Medical Device Quality Congress (MDQC) Only	$1,357		$1,597	
Preconference Workshop + MDQC	$1,527		$1,797	
Device Supplier Quality Training Session + MDQC	$1,697		$1,997	
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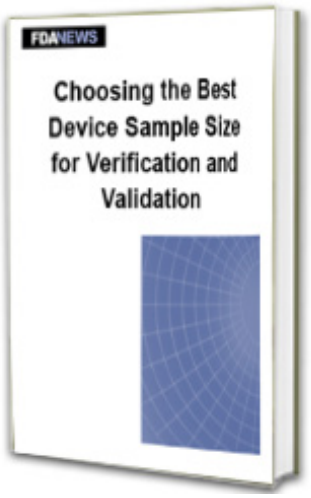

Choosing the Best Device Sample Size for Verification and Validation

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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.
- Look at variability, including variation from unit to unit or from batch to batch, as well as variation in their measurement systems.
- Design verification and validation tests, particularly regarding choice of sample size.
- Fully understand the requirements for statistical techniques, including how different techniques can affect the design control process.
- And much, much more.

Finally, you can gain a clearer understanding of how to put together a statistical methods program for design verification and validation that will satisfy FDA auditors.

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