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In This Issue

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India Steps Back on Trial Compensation Rules, Introduces Regulatory Framework for Devices

India's Ministry of Health and Family Welfare on Aug. 30 gave notice that it plans to scale back some elements of the controversial clinical trial compensation rules released early this year.

The new plan would eliminate mandated compensation for study subjects who receive no therapeutic benefit from a trial. It retains other compensation requirements, however, for subjects injured in trials.

Mark Barnes, a partner and healthcare specialist with Ropes & Gray, says he expects the compensation rules are on a fast track and will be implemented quickly, despite remaining questions such as: What's an appropriate amount of compensation? Who decides when compensation is warranted? And is there an option to appeal?

India's Central Drugs Standard Control Organization released finalized guidelines on clinical trial death and injury in January. In a backlash to the compensation policy, the U.S. National Institutes of Health said it was withdrawing from clinical trial research in India because of uncertainties posed by the new requirements (*IMDRM*, August).

Extended Reporting Timelines

Other proposed revisions to the trial rules include:

- Extending the time frame for sponsors and investigators to report serious adverse events from 10 days to 14 days;
- Extending the time for ethics committees to forward analyses and opinions of SAEs from 21 days to 30 days; and
- Extending the timeline for independent expert committees to examine SAEs and report their findings to the Drugs Controller General of India (DCGI) from 30 days to 60 days.

"The bottom line is: The notification of rulemaking about the compensation rules promises to eliminate some major problems, or solve some from the first issuance — but, we have to wait and see what the final proposed version is," Barnes says.

The Aug. 30 notification will be followed by a formal proposal, according to Barnes. The next step is for the ministry to

open the proposal to public comment, after which a final rule will be published in the *Official Gazette*. Barnes says he understands that the specific draft regulations "will be issued within days or at most a couple of weeks."

New Central Authority

The revisions to the compensation rules come one day after Indian lawmakers introduced a bill to establish a comprehensive regulatory framework for medical devices. The bill, which amends the 1940 drug and cosmetics law, would create a Central Drugs Authority (CDA) overseen by a council of permanent secretaries from related ministries. In addition to extending the clinical trial compensation rules to device trials, it also lays the groundwork for regulations on the classification, manufacture, sale, distribution, import and export of medical devices.

The new authority would operate as an independent agency similar to the U.S. Food and Drug Administration. "This idea of elevating the status of the drug control authority and the DCGI … has had a lot of discussion among the higher echelons of Indian academics and government staff for the past couple of years," Barnes notes.

Document Index

The following documents covered in this issue of the *International Medical Device Regulatory Monitor* are available for download at www.fdanews.com/IMDRMdocs.

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The new proposal authorizes the CDA to develop a risk-based classification system for devices and establishes definitions for "medical device" and "investigational device," including what constitutes an "adulterated" or "spurious" device. The bill would give the CDA authority to review, suspend or cancel any permission or license for device and drug manufacturing in the country.

The bill also authorizes the CDA to:

- Prescribe standards for different classes of devices, conformity assessment and quality assurance, and development of new devices;
- Set conditions for the import and manufacture of custom-made devices and investigational devices;
- Establish procedures for reporting adverse events, postmarketing surveillance and recalls;
- Set requirements for the approval of laboratories and conformity assessment bodies;
- Determine procedures for overseas inspections;
- Establish test methods for determining if a device conforms to standard quality;
- Prescribe types of licenses, certificates, records and documents to be maintained;
- Set labeling requirements; and
- Establish criteria for humanitarian use devices.

To enable tracing of devices in the event of a health risk or other problems, all software and device components would have to display the scientific name on the label or wrapper and have a unique device identifier.

Just what these new requirements will be and how the classification system will look are left to the CDA to determine, but past efforts to establish regulations have steered toward international guidelines such as those of the Global Harmonization Task Force.

The bill was introduced in the upper house of Parliament, which includes the Departmental Committee on Health and Family Welfare. As of press time, the legislation had not been assigned to the committee and no time frame has been established for debating it.

Barnes says industry should welcome the rulemaking legislation "because it clarifies [the government's] authority and gives [industry] a clear regulatory process rather than an ambiguous one." He adds, though, that violation of the regulatory requirements would be met with "strict" and "very tough" civil and criminal penalties. According to the bill, an adulterated device could land its maker in prison for life.

Efforts to create a regulatory regime for devices have been in the works for years, with industry expressing hope three years ago that regulations were imminent (*IMDRM*, August 2010). Earlier this year, CDSCO issued a set of 77 frequently asked questions in an attempt to provide some clarity for devicemakers, whose products are now minimally regulated under the country's drug laws (*IMDRM*, March).

View the compensation notice at www.fdanews.com/ext/files/09-13-Compensation.pdf. The Drug & Cosmetics (Amendment) Act, 2013, is at www.fdanews.com/ext/files/09-13-IndiaBill.pdf. — Nick Otto

Brazil Enacts Strict Antibribery Law, Implements New GMP Framework

Brazilian President Dilma Rousseff has signed into law legislation aimed at stemming corporate bribery of government officials across all business sectors. The law brings the country's antibribery policies in line with other major nations and the Organization for Economic Cooperation and Development (OECD).

The "Clean Company Act" requires the government to establish procedures for investigating alleged bribery and corruption and sets fines and penalties for companies that run afoul of the law. Companies found guilty of offering bribes may be fined up to 20 percent of their gross annual revenue from the previous year, or a maximum of about US $26 million. The government can also suspend or dissolve the company's operations and confiscate its assets, depending on the egregiousness of the bribes.

The law calls on competent authorities to establish policies, at the penalty phase, that take into account whether a company has a compliance program in place. Those that do could fare better than those that don't. And it calls for the establishment of credits for companies that voluntarily disclose corrupt practices.

"I think this law fills some gaps, and the legislation shows that Brazil is compliant with the international agreements," attorney Carlos Ayres, co-chair of the Brazilian Institute of Business Law's anticorruption and compliance committee, tells *IMDRM*.

The legislation was prompted by a 2007 peer review of Brazil's anticorruption efforts by the OECD's Antibribery Convention, Ayres says. While not an OECD member, Brazil has participated with the convention and was asked to take "urgent steps" to make companies liable for bribing foreign officials.

"This new law is a tough law," Ayres says. The government needs only to show that bribes were paid — a lower bar for prosecution than the U.S. Foreign Corrupt Practices Act, which requires the government to also show intent to corrupt.

Decentralized Enforcement

Before signing the bill on Aug. 1, Rousseff vetoed three provisions she believed would weaken the law. For instance, the legislation approved by the Brazilian Senate would have limited financial liability to the value of the contract obtained with the bribe. Rousseff said this could impair the government's ability to "effectively punish offenders and deter future violations."

Also nixed were provisions on the establishment of intent and on leniency for less-extensive crimes.

The new law says nothing about gift-giving. Ayres says a law already on the books limits company gifts to public officials to about US $45.

The "Clean Company Act" will be enforced by the compliance offices of the competent authorities responsible for various market segments, Ayres said. Devicemakers will answer to investigators from the Ministry of Health. During debate on the bill, industry had asked that a neutral, centralized agency handle the inspections, to avoid the potential for conflicts of interest.

Brazil's law comes as other governments have been cracking down on foreign corrupt practices. The most recent case, involving China's investigation of UK pharma giant GlaxoSmithKline, has now mushroomed into an industrywide probe that includes devicemakers (*IMDRM*, August) (*see story, page 12*).

GMPs Revised

Separately, Rousseff signed a decree giving Anvisa the authority to implement a new good manufacturing practice framework that is more in line with U.S. drug and device GMP.

The new framework "corrects the root problem of the GMP certificate problem," whereby companies had to have a Brazilian GMP certificate in order to register their products, says Marcelo Antunes, regulatory affairs strategy consultant with SQR Consulting in São Paulo. The problem stemmed from a 1988 decree that "explicitly tied the presentation of the B-GMP certificate to the registration," Antunes notes.

Among other changes, the new GMP framework:

- Eliminates certain requirements limiting registration transfers and gives Anvisa additional authority to define other options to transfer registrations; and
- Permits manufacturers to outsource the quality control of products to third parties that adhere to criteria defined by Anvisa.

View Brazil's "Clean Company Act," in Portuguese, at www.fdanews.com/ext/files/09-13-Brazil.pdf. The GMP decree, published in the Aug. 14 *National Gazette*, is at www.fdanews.com/ext/files/09-13-BrazilGMP.pdf. — Nick Otto

Public Health Group Wants EU Device, Drug Traceability Systems Aligned

In a run-up to the EU Parliament's public health committee vote on draft medical device regulations later this month, a public health group is urging that a proposed unique device identification system be compatible with the existing traceability system for drugs to avoid parallel processes and higher costs.

Putting UDI in place will "ensure a high level of safety and a more transparent system in order to restore patients', consumers' and healthcare professionals' confidence" following the PIP breast implant debacle and other high profile cases involving faulty medical devices, the European Public Health Alliance says.

EPHA also urges that the databank used to house UDI information be "robust, transparent and user-friendly," and suggests that patients and healthcare professionals be consulted during its development to ensure end user needs are adequately met.

The group seeks more clarity on the regulations' scope, noting that some borderline cases involving devices and drugs are classified differently from one member state to another. "To put an end to such unnecessary discrepancies, the proposed Medical Devices Coordination Group should pool its expertise of national legislations and provide solid advice on the most suitable classification decision," EPHA writes.

EPHA supports most of the European Commission's proposals to strengthen the current legislative framework, including a premarket scrutiny mechanism for high-risk devices and more oversight of notified bodies (*IMDRM*, October 2012). However, the group believes that centralized authorization of the riskiest devices — proposed by the rapporteur for the medical device regulation — could slow life-saving devices' path to market without any added benefit to safety or quality (*IMDRM*, May).

EPHA also recommends that:

- Notified bodies specialize in certain categories of devices;
- Vigilance reporting include adverse events caused by replacement parts or components, not just the entire device;
- The MDCG's duties be broadened to include expertise for decisions relating to postmarket surveillance and other sensitive issues;
- Patients have access to "unequivocal information" regarding reprocessing of devices; and
- The format and language of instructions and packaging for self tests be user-friendly and understandable for lay persons.

The Committee on the Environment, Public Health and Food Safety is scheduled to vote on the proposals Sept. 18 (*IMDRM*, July).

View EPHA's position paper on the device and IVD regulations at www.fdanews.com/ext/files/09-13-EPHA.pdf. — Nick Otto

EU Lawmakers Set to Vote on EMC, Measuring Device Directives

Manufacturers of electrical devices could face new supply chain controls under a proposed recast of the EU's electromagnetic compatibility directive. As *IMDRM* went to press, the Parliament's internal markets committee was set to vote on the proposal.

The controls are "inevitable," as they are going to apply to all CE-marked goods, said Erik Vollebregt, a partner at Axon Lawyers in the Netherlands.

Language in the proposal would put the onus on devicemakers to ensure their distributors comply with the directive and that end users won't be harmed. "Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient," the proposal states. The aim is to enable authorities to trace noncompliant products on the market back to the manufacturer.

Other changes to the directive relate to the presumption of conformity provided by harmonized standards, notified bodies and conformity assessment procedures.

The committee is also slated to vote on a recast of directives on low-voltage electrical equipment and measuring instruments. Stakeholders have pushed for the EU to align overlapping sections in all three directives (*IMDRM*, May 2012). — Nick Otto

Malaysia Issues Final Guideline On Device Registration

Malaysia's Medical Device Authority has released a six-step guideline on registering devices through the regulator's web-based system.

Companies should determine whether the product is a medical device under the 2012 device law and then determine its appropriate classification and group. Next, they should conduct a conformity assessment and compile evidence of conformity with MDA regulations in a common submission technical document.

The conformity assessment must be conducted by an approved conformity assessment body. The MDA has approved three thus far: BSI Services Malaysia, SGS and SIRIM QAS. Another seven have applications pending with the agency.

Applications should be submitted through the Medical Device Centralized Online Application System, or MeDC@St, which was launched July 1 to ease compliance with requirements of the 2012 Medical Device Act (*IMDRM*, July).

In addition to general manufacturer information, the dossier and declaration of conformity, the MDA asks manufacturers to include a history of the device's postmarket vigilance history. Devicemakers should also supply the products recall history, adverse event reports, removal from other markets, if applicable, and any postmarket surveillance studies.

Earlier this year, MDA issued guidelines on good distribution practices (*IMDRM*, August).

The registration guideline, which is aligned with the Association of Southeast Asian Nations, took effect July 1. View it at www.fdanews.com/ext/files/09-13-Malaysia.pdf. The list of conformity assessment bodies is at www.fdanews.com/ext/files/09-13-MalaysiaCAB.pdf. — Nick Otto

Final Guidance Clarifies U.S. FDA Ideas On Risk-Based Clinical Trial Monitoring

The U.S. Food and Drug Administration has finalized guidance on centralized and risk-based approaches to monitoring clinical trials. The document, which emphasizes the importance of data integrity and human subject protection, reflects the agency's view that on-site monitoring is not always needed or preferable.

The Aug. 7 guidance covers the basic elements of monitoring plans, which should include details about the methods used, sponsors' responsibilities and trial requirements. Plans should also state the specific risks that need to be monitored and include sufficient information to enable monitors to do their jobs. All relevant sponsor and contract research organization (CRO) personnel should review the monitoring plan and its associated documents, the guidance says.

When developing the monitoring plan, sponsors must take into consideration the complexity of the design, types of study endpoints, clinical complexity of the cohort, geographic considerations, investigator experience, capabilities of the electronic data capture systems, safety profile of the investigational device, study stage and quantity of managed data.

The FDA describes monitoring as a "quality control" tool that can help determine if a study is being conducted as planned. However, quality cannot be ensured by monitoring alone and must be built into the trial, the guidance notes. The agency is considering the need for additional guidance describing a quality-based risk-management approach to clinical trials.

The final guidance puts greater emphasis on centralized monitoring compared with what was feasible when the International Conference on Harmonisation issued its good clinical practice guideline, ICH E6, in 1996. But advances in technology and the growing use of electronic records now provide remote access to trial data, the FDA says.

"We expect the … device industries will, for the foreseeable future, continue to use some amount of on-site monitoring, but we anticipate decreased use of on-site monitoring with evolving monitoring methods and technological capabilities," the guidance adds.

The final version drops a proposed process whereby sponsors could voluntarily submit their monitoring plans to the Center for Devices and Radiological Health for feedback. FDA spokesman Stephen King says numerous stakeholders objected to the lack of specific details in the process proposed in the draft and said it could delay the start of clinical trials. After reviewing the comments, the agency concluded it lacks the resources to manage such a process.

The final document says devicemakers may file a presubmission request for feedback or contact CDRH's Division of Bioresearch Monitoring.

Comments on the draft also cited the lack of specific information on development and initialization of risk-assessment plans, appropriate mitigation plans and execution of mitigation plans through the monitoring plan. "In response … the FDA included additional detail on the development of a monitoring plan, which focuses on the important and likely risks, identified by the risk assessment, to critical data and processes," King tells *IMDRM*. The final guidance also offers more detail on the steps involved in performing a risk assessment and provides references to tools and methodologies that can be used to conduct a risk evaluation.

Risk-Based Is Competitive

While the U.S. National Institutes of Health has long used risk-based monitoring, the concept is still relatively new to commercial clinical research. Lynn King, assistant vice president of operations at Rho, a Chapel Hill, N.C.-based CRO, welcomed the final guidance, telling *IMDRM* it provides industry with further certainty as to what monitoring plans will pass muster. It also encourages an approach to monitoring that will keep companies competitive and help cut trial costs.

"Site visits will always be important," Lynn King says. "Some things cannot be verified remotely ... but a risk-based approach with good judgment and sound reasoning can greatly reduce the frequency of [site] visits." In a best-case scenario, sponsors may be able to replace the current standard of visiting a site every four to six weeks with one visit a year, she says.

Read the final guidance at www.fdanews.com/ext/files/08-06-13-RiskGuidance.pdf. — Ferdous Al-Faruque

Industry to TGA: Postmarket Surveillance, Registries Best Way to Assure Device Safety

Australia's Therapeutic Goods Administration should focus on postmarket surveillance and the use of appropriate registries to assure the safety of high-risk medical devices, rather than add a new layer of premarket controls, industry stakeholders say. The press for stricter scrutiny follows the PIP breast implant and metal-on-metal hip scandals that also fueled an overhaul of EU device regulations.

Earlier this year, the TGA floated three options for enhancing device scrutiny: maintain the current system as is, make changes to the premarket assessment of medical devices, or expand TGA mandatory conformity assessments for active implantable medical devices and Class III implantable devices and permit third-party assessments for other devices except Class IV in vitro diagnostics (*IMDRM*, February).

The agency favors Option 2, which would expand the range of high-risk devices targeted for mandatory audits to some Class IIb implantable and long-term surgically invasive devices, and introduce a new Level 3 audit for AIMD and Class III implantable devices, with associated fees. Option 2 would also require publication of all device regulatory decisions and permit non-TGA conformity assessment for Aussie manufacturers of all but Class IV IVDs (*IMDRM*, June).

In comments to the TGA, Medtronic says that increased premarket scrutiny would not have prevented either the PIP or metal hip failures. "PIP was fraud and cannot be regulated against," the company writes. The hip issues were detected through postmarket surveillance and use of a targeted registry, Medtronic adds.

Moreover, AIMD and Class III implants are already subjected to high-level conformity assessment by notified bodies, including a full design review, and account for a small percentage of field correct actions, Medtronic says. The devicemaker proposes a fourth option.

Under Medtronic's proposal, AIMDs and Class III implantable devices would be subject to increased postmarket surveillance and the use of registries, while Class IIb implantables would undergo expanded Level 2 mandatory audits. All regulatory decisions would be transparent. Medtronic agrees that third-party conformity assessments should be allowed, but says the TGA should "actively" seek details on how the European Commission designates notified bodies.

BSI also supports acceptance of third-party conformity assessments and said confidence-building activities by notified bodies could allow more high-risk devices to undergo Level 1 or 2 audits. This would enable the TGA to focus attention on notified bodies whose reviews are not up to TGA standards, the group writes.

"Additionally, the confidence building program will allow the TGA to gain a further insight into how notified bodies review high risk devices and … learn valuable lessons that can only be obtained by working with the best notified bodies," BSI says.

The Medical Technology Association of Australia weighed in on the reform proposals earlier this summer, saying the current regulations are sufficient to ensure the safety of devices, but the TGA isn't using all

the means it has — such as adverse event reporting and international vigilance exchange — to monitor high-risk devices (*IMDRM*, July).

View Medtronic's and BSI's responses, respectively, at www.fdanews.com/ext/files/09-13-Medtronic.pdf and www.fdanews.com/ext/files/09-13-BSI.pdf. — Nick Otto

Aussie Devicemakers Call for Clarity, Flexibility in IMDRF UDI Guidance

A proposed guidance on unique device identification should not limit the number of accredited global organizations and available coding systems devicemakers can use, an industry group says.

"As long as the systems meet the ISO standard and are accredited, there should be no reason to limit the numbers," the Medical Technology Association of Australia writes in comments on the International Medical Device Regulators Forum guidance.

MTAA notes, for example, that the UDI database called for in the U.S. Food and Drug Administration's proposed rule might not capture device identifiers and product identifiers for products made and supplied outside the U.S. IMDRF should recognize that supply chain and logistics operators will utilize all available systems in the international market, the group says.

Global Adoption

MTAA also notes that while globally recognized device identifiers are a good idea, the system's success depends on its global adoption throughout a supply chain network. The trade group gives the example of a logistics supplier being able to use UDI to accurately store and deliver a product, but the hospitals it supplies may not have the technology to record the UDI in patients' records at the point when the device is used.

Eucomed also submitted comments on IMDRF's UDI consultation, focusing on issues that define consistent, worldwide requirements in order to facilitate the implementation of a global and interoperable UDI system — such as a core set of UDI data elements and consistent marking requirements, industry spokesman Thomas Lindemans tells *IMDRM*. Eucomed is planning to discuss its proposed changes at IMDRF's Sept. 16 meeting in Washington, D.C.

IMDRF released its UDI plan in April, characterizing it as a "highly interoperable" and harmonized system for globally tracking medical devices. The release dovetailed with the European Commission's recommendation for an EU-wide UDI system (*IMDRM*, May).

Both plans appear to be closely aligned with the FDA's proposed rule and suggest regulators are serious about minimizing divergences in track-and-trace systems that could impede the flow of devices in international markets (*IMDRM*, August 2012). The FDA missed its May 7 deadline for issuing a final rule; the rule is currently awaiting release from the Office of Management and Budget (*IMDRM*, July).

Auditing Organizations

MTAA also takes issue with IMDRF's draft guidance on recognition and monitoring of auditing organizations, questioning language in the draft that suggests fast-track approvals may be influenced by commercial pressures. The group asks IMDRF to prove that claim or remove the text (*IMDRM*, November 2012).

"Fast track reviews for QMS certification still involve site audits," MTAA writes. "Is there evidence to support this clause? Have there been instances where fast tracking has compromised impartiality?"

The group also seeks more clarity on situations where the auditing organization and regulatory authority reviewing a device are the same. The guidance would require auditing organizations to confirm they don't provide certification when conflicts of interest threaten impartiality, such as a wholly owned subsidiary of the auditing organization requesting certification from its parent.

At an FDAnews conference earlier this summer, the FDA's Kimberly Trautman, who chairs IMDRF's single-audit committee, said the program could save devicemakers money by minimizing the number of times a plant is disrupted by inspectors (*IMDRM*, July). "If you have problems, you could be in trouble in four jurisdictions," she said.

Consultations have also closed on *Regulated product submission (RPS) Table of contents* and *Standalone Software: Key Definitions*. — Nick Otto

U.S. FDA: Wireless Device Guidance Focuses on Interference, Risk Mitigation

Developers of wireless medical devices need to consider whether their products will play well with other devices sharing the same radio band, a U.S. Food and Drug Administration guidance says. The document outlines steps to ensure wireless devices transmit data correctly, securely and on time.

In issuing the guidance, the FDA cites the growing use of medical devices in electromagnetic environments that contain multiple sources of radiofrequency (RF) energy. This increases the likelihood that emissions from one device could interfere with the functioning of another, the agency says.

The Aug. 14 guidance finalizes a draft version issued in January 2007 (*IMDRM*, February 2007). Among other changes, the FDA has clarified and expanded the scope of RF wireless technology covered by the guidance to include wireless medical telemetry service (WMTS); medical device radiocommunication service (MedRadio), including the former medical implant communication service (MICS); medical micropower network (MMN) and medical body area network (MBAN); cellular communication chipsets; and RF identification products.

The final guidance also responds to industry comments by addressing general design factors affecting wireless quality of service (QOS), such as acceptable latency, acceptable level of probability for loss of information within the network, accessibility and signal priorities of the network.

"When the network is chosen or designated, FDA recommends use of a risk-management approach to deployment, security, and maintenance of the network's QOS. Depending on the intended use of the device, additional failure modes may need to be considered," the guidance states. Once failure modes and associated risks are identified, companies should justify the acceptable risk or demonstrate appropriate risk mitigation, the agency adds.

According to the guidance, developers of wireless devices need to consider a range of possible hazards that could put patients at risk. These include poorly characterized or poorly used wireless systems; lost, corrupted, or delayed transmissions; transmissions that are damaged by competing signals or other interference; lack of wireless security; and the potential for misuse due to missing or inadequate instructions for use.

Risk Analysis

Design engineers should look at RF safety issues during risk analysis, using reports of electromagnetic interference-related events to estimate the probability of occurrence. Design validation studies should include a risk analysis of wireless communications and control functions, the FDA says. The risk analysis should also examine the risks the device may pose to patients and other devices and the possible impact of unexpected interference. Results of final RF wireless and electromagnetic compatibility (EMC) testing should be included in the 510(k) or PMA.

Further, companies should ensure that the wireless technology's capabilities and expected performance match the functions and intended uses of the device, the guidance says. To assure data integrity, companies should incorporate error control processes, with parameters such as bit error rate, packet loss and signal-to-noise-ratio standing as useful tools to assure data integrity.

When choosing an RF wireless frequency band or a commercial wireless radio component, the FDA suggests devicemakers look at international band allocations and whether the device needs primary or secondary radio service classification. Companies should also look at how other uses already on the band might affect their devices, the guidance says. And they should consider interface mitigation techniques for shared bands and tissue propagation and absorption rates for devices that are implanted or worn on the body. If a commercial RF component is used, devicemakers should verify that the component has been tested for use in medical equipment.

Manufacturers should provide detailed information in the labeling on how to set up and operate their wireless devices. The FDA recommends including the following:

- Summary of the device's wireless functions and specific incorporated wireless technology;
- Discussion of the wireless technology's operating characteristics, effective RF-radiated power output, operating range, modulation and bandwidth of the receiving section;
- Description of wireless QOS required for safe and effective operation;
- Description of recommended wireless security measures, such as encryption;
- Steps to take if wireless problems occur;
- Details on how to handle possible wireless coexistence issues, including mitigating steps;
- Compliance with EMC and telecommunications standards and test results summary;
- RF information required by the U.S. Federal Communications Commission; and
- Warnings about possible risks from other RF sources near the device, such as security systems or cellular phones.

Government concerns over wireless device networking have grown in recent years as the systems have become more common. In May, the FCC announced a set of licensing changes that make it easier for healthcare facilities to test new wireless devices. This followed a September 2012 decision to dedicate part of the RF spectrum for use by medical devices.

View the final guidance at www.fdanews.com/ext/files/08-19-13-radio.pdf. — Elizabeth Orr

U.S. FDA Unveils FY '14 User Fees; PMAs Jump More Than $10K

The U.S. Food and Drug Administration has released user fee rates for fiscal 2014. The fees, which apply from Oct. 1 through Sept. 30, 2014, were originally laid out in last year's Medical Device User Fee Act legislation and have been adjusted for inflation.

The new fees are:

- Base fee for PMA: $258,520;
- Panel-track supplement: $193,890;
- 180-day supplement: $38,778;
- Real-time supplement: $18,096;
- 30-day notice: $4,136;
- 510(k): $5,170;
- 513(g) request for classification information: $3,490;

- Annual periodic reporting fee for Class III device: $9,048; and
- Annual registration fee: $3,313.

Devicemakers will pay just $99 more for a 510(k) in fiscal 2014, but a whopping $10,520 more for a PMA (*IMDRM*, September 2012). The $738 increase in establishment registration fees, from $2,575 this year, includes $43 to prevent a revenue shortfall, the FDA says.

Small businesses — those with gross sales below $100 million for the most recent tax year — pay 25 percent of the standard fee for all filings except 501(k)s, 30-day notices and 513(g)s, for which they pay 50 percent. They do not get a discount on the annual registration fee.

An FDA guidance detailing the new fees is available at www.fdanews.com/ext/files/08-05-13-userfees.pdf. — Elizabeth Orr

UK Cost Watchdog OKs Test to Speed Post-Cancer Surgery Results

The UK's National Institute for Health and Care Excellence says women with breast cancer should have access to a test that lessens the wait between surgery and learning if the disease has spread.

The new test gives more rapid results to waiting surgeons and analyzes the whole lymph node, reducing the chance that tiny particles of cancer are missed, an Aug. 7 guidance by the cost-benefit agency says. NICE's recommendations help to shape the government's coverage decisions.

The RD-100i OSNA system, manufactured by Sysmex UK, is a real-time, intraoperative test used during surgery to detect the presence of biological markers that suggest the spread of breast cancer.

Currently, patients having breast cancer surgery have lymph nodes removed from their armpit to test if cancer cells have spread from the main tumor. Getting the results can take two weeks or longer. By contrast, OSNA can determine whether cancer cells are present, using half a lymph node, in 30 to 45 minutes, depending on the number of nodes analyzed, the guidance notes. Results are expressed quantitatively and qualitatively.

"For people with breast cancer and their families, waiting to hear if the disease has spread can cause significant distress and anxiety," said Carole Longson, director of NICE's Health Technology Evaluation Center. "If the test is positive and a second operation is needed to remove more of the axillary lymph nodes, the second operation can be technically more difficult and result in a higher risk of complications."

National Registry Urged

The positive recommendation was based on 16 studies on OSNA's effectiveness in detecting metastases in sentinel or axillary lymph nodes. Of those, 14 reported test accuracy as an outcome and two of those also reported time-to-analysis.

The range of estimates for sensitivity and specificity by patients before adjustment for tissue allocation bias from the studies was 77.8 to 80 percent and 88 to 97.2 percent, respectively, the guidance says. After adjusting for tissue allocation, the range of estimates for sensitivity and specificity was 89.8 to 100 percent and 93.3 to 97.2 percent, respectively.

Looking at long-term results, NICE's Diagnostics Advisory Committee found that the incremental cost-effectiveness ratio for OSNA ranged from about US $3,283 saved per quality-adjusted life year lost when the test's sensitivity was 70 percent, to about $21,991 saved per QALY when OSNA's sensitivity was 90 percent. "At 100 percent sensitivity, OSNA dominated histopathology, having more QALYs gained and lower costs," the guidance says.

NICE recommends that a national registry be developed to collect data on OSNA's success in detecting sentinel lymph node metastases during breast cancer surgery. The registry should include data on all patients having whole lymph node analysis via the OSNA system and should be integrated with other breast cancer registries, the agency says.

According to NICE, about 11,000 women with newly diagnosed breast cancer require further surgery to deal with affected lymph nodes each year in the UK.

View the guidance at www.fdanews.com/ext/files/09-13-OSNA.pdf. — Nick Otto

Orphan Sponsors to Get One-on-One Talks With U.S. FDA, EMA Officials

The U.S. Food and Drug Administration and European Medicines Agency will hold a joint workshop this fall for developers of orphan medical products to discuss both agencies' rare disease programs.

In addition to overview sessions by each regulator, device- and drugmakers will have the opportunity on

Oct. 4 to register for one-on-one video teleconferences with FDA and EMA staff. During those meetings, sponsors will be able to discuss specifics on applying for an orphan product grant or designation.

The workshop itself will feature two simultaneous sessions in the morning: an overview of both regulators' orphan drug designation programs and an overview of the FDA's orphan designation and grant programs for medical devices. Both sessions will be available by webcast.

Earlier this year, the FDA finalized a 2012 draft guidance for devicemakers seeking a humanitarian use device designation for an orphan subset (*IMDRM*, January 2012).

Under the guidance, HUD designations are available for devices intended to treat or diagnose a condition that affects fewer than 4,000 Americans a year. For in vitro diagnostics, the 4,000 limit applies to patients who would get the test, not the number of patients diagnosed with an orphan condition.

For more information and to register, visit www.fdanews.com/ext/files/08-21-13-Orphan.pdf.
— Nick Otto

IN BRIEF

China Probe Could Spill Over to Devices

Chinese government officials are reportedly investigating unfair competition in the device industry as part of a broader antibribery probe. The State Administration for Industry and Commerce launched the investigation last month and said it will run through November. Sources say it is likely to include an investigation of hospitals that purchase big-ticket medtech items and then don't use them. The probe follows on the heels of an inquiry into alleged bribes paid to government officials by pharma giant GlaxoSmithKline (*IMDRM*, August). "China needs to improve [the] transparency and make sure there is no bribery in this life-critical industry," says Daniel Huang, a quality systems and regulatory affairs officer at Celestica.

Russia Joins Device Harmonization Group

Russia's Roszdravnadzor has joined the International Medical Device Regulators Forum, becoming its eighth member. The agency sent the IMDRF chair a letter accepting full membership on the forum's management committee as spelled out in a 2011 invitation, Kimberly Trautman, the U.S. Food and Drug Administration's representative, said. China, which joined IMDRF earlier this year, and Russia had been observing members. The World Health Organization, Asian Harmonization Working Party and Asia-Pacific Economic Cooperation currently sit as observing organizations. Trautman said IMDRF is developing a set of procedures for regulators seeking full membership in the harmonization group.

Peru Renews ISO 9001:2008 Certification

Peru's drugs and medical devices regulator DIGEMID has renewed its ISO 9001:2008 quality systems management certification. The renewal, valid through 2016, was granted by ICONTEC, a multinational conformity assessment body based in Colombia.

ANMAT Raises Medical Device Fees

Argentina's ANMAT is raising fees for devices listed on the Register of Producers and Medical Technology. Effective Dec. 31, Class I devices that are marketed in Argentina will pay a US $400 registration fee, Class II devices will pay $550, Class III devices will pay $700 and Class IV in vitro diagnostic devices will pay $1,000. Fees to maintain registration of a product not currently marketed in the country are $300 for Class I, $450 for Class II, $600 for Class III and $900 for Class IV diagnostics.

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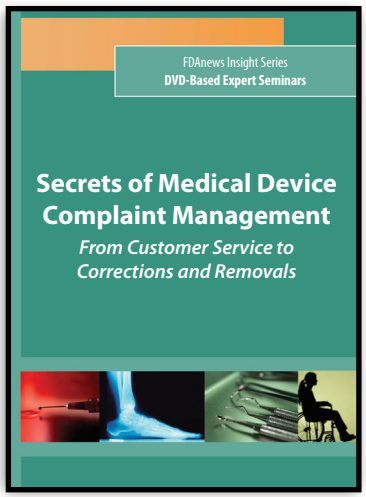

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An Interactive Workshop Featuring 5 Tools and Discussion of 4 Emerging Standards

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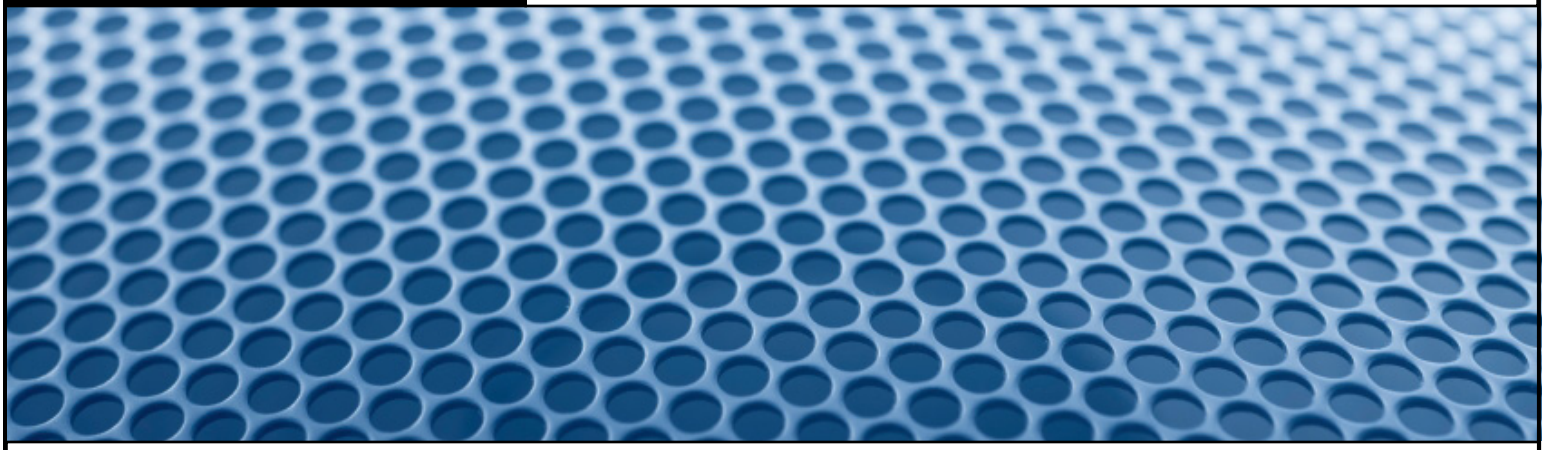

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Medical Device Risk Management

Beyond FMEA — New Tools to Assure Your Risk Management Program Meets New Standards

Attend this invaluable workshop to learn:

- How to use ETA, FTA, HACCP, PHA and HAZOP to transform your risk management program.
- How the FDA and international regulatory bodies measure the severity of a risk and the different levels of seriousness.
- How to create and administer a risk management file — think of it as your risk management file cabinet.
- Understand how to score risks and create a risk "scorecard" using severity and probability.
- Tips and a checklist to assure that all your risk management reports contain the information all reports should have.

YOUR EXPERT INSTRUCTOR

DAN O'LEARY has more than 30 years experience in quality, operations and program management in regulated industries, including aviation, defense, medical devices and clinical labs. Mr. O'Leary is the president of Ombu Enterprises, a consultancy focused on operational excellence and regulatory compliance serving small manufacturing companies.

The FDA's QSR expert, Kim Trautman, on risk management:

"Are FMEA or FMECA… good tools? Yes. They are very good tools that can be utilized. Are they in and of themselves a risk management system? Absolutely not. I can't tell you how many manufacturers I have seen that have tried to present their risk management system by simply presenting a FMEA — that is not a risk management system. Do not make the mistake of presenting FMEAs as your whole risk management system."

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WORKSHOP AGENDA

DAY ONE

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

9:00 a.m. – 10:15 a.m. Workshop Introduction and Concepts of Risk Management Overview

- The fundamentals of medical device risk management
  - Define common risk factors
  - Create a Consequence Diagram and extend it to multiple levels to build a Decision Tree
- Components of risk and potential problems to consider
  - The neonatal heal warmer example: an illustration of a Risk Analysis Procedure
- Definitions from ISO 14971:2007
  - Discuss the definition of a hazard and a harm
  - Risk defined: Identify the probability of harm and its severity to estimate risk
  - Assess the risk, including its formal definition
- Why FMEA is not sufficient for risk management

10:15 a.m. – 10:30 a.m. BREAK

10:30 a.m. – 11:00 a.m. INTERACTIVE EXERCISE
Importance of Risk Management — This exercise allows for an exchange of ideas among participants. They will discuss why risk is important and provide an example of failed risk management. They will discuss the various approaches their firms take to recognize the amount of impact and loss by developing three bullet points that describe the approach.

11:00 a.m. – 11:30 a.m. The Regulatory Structure: The Current Status of ISO 14971:2007

- ISO 14971:2007 as the current standard
  - Follow the development of ISO 14971:2007 and understand the new requirements
  - Outline the steps in the risk management process
  - First look at the implications of EN ISO 14971:2012
- The risk management requirements in FDA's QSR — Design Validation
  - Understand how risk management supports design validation
  - Recognized consensus standards and the FDA's declaration of conformity
- The Risk Management requirements in ISO 13485:2003
- Risk Management standards in the EU
  - Where to find the harmonized standards to the Medical Device Directive
  - Understand the status of EN ISO 14971:2012 and EN ISO 13485:2012
- Global Harmonization Task Force: Two important guidance documents for risk management
  - Understand the purpose of GHTF and its successor, IMDRF
  - Implementation of risk management principles and activities within a quality management system
  - Explore the purpose of the guidance; review and identify the four phases of risk
  - Highlight the two most important elements within the document
  - Identify essential principles of safety and performance of medical devices
- Review FDA warning letters
- Evaluate examples from companies that failed to address and design a valid risk analysis

11:30 a.m. – 12:00 p.m. Understanding ISO 14971:2007 (Part 1)

- Overview of the structure of ISO 14971:2007
- Explore the parts of a risk management plan: scope, responsibility, review, risk acceptability, risk verification, production activity, post-production activity
- How to create and administer a risk management file — Think of it as your risk management file cabinet
- Analysis of clauses 4–9 in ISO 14971
  - Ways to create a risk analysis (Clause 4)
  - Outline a risk evaluation (Clause 5)
  - Determine whether a risk reduction is required (Clause 6)
  - Highlight the importance of a residual risk evaluation (Clause 7)
  - Learn about the report on risk management of a device (Clause 8)
  - Look at production and post-production information (Clause 9)
- Components of risk — How to measure risk through hazards that create harm

12:00 p.m. – 1:00 p.m. LUNCH BREAK

1:00 p.m. – 1:30 p.m. Understanding ISO 14971:2007 (Part 2)

- Conclusion of Understanding ISO 14971:2007

1:30 p.m. – 2:30 p.m. Building a Risk Management File That Meets ISO 14971:2007 Requirements (Part 1)

- Understanding the purpose and contents of a risk management file
  - Assuring the file contains pointers to all relevant documents
  - Organizing documents by hazard and cause
  - Auditing the risk management file
- Risk management planning
  - Explore the role of the risk management plan and learn the scope of the plan
  - Designating someone to be responsible for the plan: qualifications for performing risk management tasks, RASI Matrix and example
  - Two sets of criteria for risk acceptability
  - Accessing risk severity and probability
  - Monitoring residual risk evaluations
  - Two aspects of verification activities provided in the standard
  - Post-production activity: how to collect data and review
- Hazard Analysis
  - Why FMEA is not the right approach
  - Hazards that are not failures
  - The fallacy of Risk Priority Numbers (RPN)
- Risk Assessment
  - Two parts of risk assessment: risk analysis and risk evaluation
  - Tips to develop a systematic approach to determine risk
  - Different components of risk
  - Tools for hazard identification — 5 standard methods to support risk analysis (PHA, FTA, FMEA, HAZOP, HACCP)
  - Understand how to score risks — how to use severity and probability

2:30 p.m. – 2:45 p.m. BREAK

2:45 p.m. – 3:45 p.m. INTERACTIVE EXERCISE
The Risk Management Plan — Participants will develop various sections of the plan based on the contents of a file as defined in ISO 14971. They will first develop a risk matrix. They will then define the structure of their matrix and include a description of each part. Finally, they will devise a plan for data collection, analysis and use of production and post-production issues and discuss how to incorporate it into the risk management file.

3:45 p.m. – 4:30 p.m. Building a Risk Management File That Meets ISO 14971:2007 Requirements (Part 2)

- Risk control
- Conducting a risk control completeness check
- Implementing risk controls: Strategies for the two elements of risk verification
- Overall residual risk evaluation
  - Seven methods to evaluate overall residual risk

Risk Management

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- Disclosing overall residual risk
- Risk management report
  - Strategies for reviewing the risk management process to ensure complete reports
  - A checklist to ensure your report is complete
- Production and post–production information
  - Review the production phase and the post–production phase
  - Evaluating final hazards and corrective processes to put in place

4:30 p.m. SESSION WRAP-UP, END OF DAY ONE DAY TWO

DAY TWO

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

9:00 A.M. – 10:00 A.M. INTERACTIVE EXERCISE
The Risk Management Report — This is a set of exercises designed to illustrate the sections of the report. Participants will develop various sections of the report based on the contents defined in ISO 14971. They will begin with deciding on someone to prepare the report. Then they will compose a checklist that acts as a guideline in reviewing the risk management plan. Finally, they will explore more about the residual risk evaluation.

10:00 a.m. – 12:00 p.m. (Includes a break)
Digging Deep Into the Risk Management Tool Kit

- Preliminary Hazard Analysis (PHA)
  - What is PHA and how can it be best used?
  - Developing a PHA worksheet
  - Sources of hazards using PHAs
- Hazard and Operability Studies (HAZOP)
  - Procedures for HAZOP
  - Developing a worksheet for HAZOP
  - Significant parameters for HAZOP
- Hazard Analysis and Critical Control Points (HACCP)
  - Using HACCP to identify hazards, establish controls, and monitor processes
  - Linking HACCP with corrective action
- Failure Modes, Effects and Criticality Analysis (FMECA)
  - Applications to discover known and probable failures in products and the failure impact
- Fault Tree Analysis (FTA)
  - Using this tool to analyze a particular event and its causes
- Event Tree Analysis (ETA)
  - Using this tool to evaluate barriers as risk reduction methods

12:00 p.m. – 1:00 p.m. LUNCH BREAK

1:00 p.m. – 2:30 p.m. APPLICATIONS IN THE EUROPEAN UNION
Understanding the 13485 and 14971 Applications to the Product Directives — From the EU harmonized EN ISO 13485:2012 and EN ISO 14971:2012 to the three product directives: MDD, IVDD, and AIMDD.

- Learn where ISO 14971:2007 deviates from the essential requirements and the implications for risk management
- Understand the linkages between conformity assessment and ISO 13485:2003

2:30 p.m. – 2:45 p.m. BREAK

2:45 p.m. – 4:15 p.m. Related Standards
There are standards and FDA guidance documents that relate to risk management and often call out ISO 14971:2007.

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62304 Medical device software – Software life-cycle processes
- FDA Guidance – Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications
- FDA Draft Guidance – Applying Human Factors and Usability Engineering to Optimize Medical Device Design
- The Assurance Case as a new methodology

4:15 p.m. – 4:30 p.m. Summary, Conclusions, and Lessons Learned

4:30 p.m. ADJOURN WORKSHOP

"Overall for me it was a valuable workshop. There was a ton of information delivered in the 2 days. The handouts and 3ring binder will be a helpful resource upon return tho my company." –Barry Shaw, Quality, Arsenal Medical/ 480 Biomedical

[Dan] provided the material in an easy to handle method and the workbook is a good take-home reference." –Philip DiMascio, Quality Engineer, Covidien

WHO SHOULD ATTEND

- Project managers involved in design and development
- Design engineers
- Quality engineers
- Manufacturing engineers
- Quality auditors
- Production managers
- Scientists involved in device research and development
- Medical staff evaluating risk, safety or effectiveness
- Quality or regulatory staff assigned to complaint, CAPA or MDR management
- Training personnel
- General/corporate counsel

COURSE BINDER MATERIALS

- Slides from PowerPoint presentations
- Case review worksheets
- Interactive exercise worksheets
- Reference docs:
  - Design Control Guidance for Medical Device Manufacturers
  - Medical Device Use — Safety: Incorporating Human Factors Engineering into Risk Management
  - Medical Device Quality Systems Manuals: A Small Entity Compliance Guide
  - Essential Principles of Safety and Performance of Medical Devices
  - Implementation of Risk Management Principles and Activities Within a Quality Management System

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