INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE



## FDA Won't Regulate Wellness Apps, New Draft Guidance Confirms

Weight management apps and products like them won't have to comply with FDA device regulations because they pose a low risk to the user and make claims related to general health issues, rather than claiming to treat a specific disease.

The agency announced its decision in draft guidance on "general wellness products," which relate to a general state of health, such as visual acuity, or chronic diseases where healthy lifestyle choices play a role in preventing the disease.

The FDA says it will not review general wellness products to see if they are devices and will not require them to comply with requirements for registration, listing, labeling, GMPs or premarket and postmarket notification.

Friday's guidance steps back from the agency's earlier position that it can regulate any product that claims to treat a specific disease or condition, saying the "mere mention of a disease in promotional materials" no longer means that FDA can regulate a device.

### 'Common Sense Line'

"FDA has chosen to draw a very common sense line that avoids regulating products that help people manage common chronic diseases," says attorney Bradley Merrill Thompson of Epstein, Becker, Green. He expects the draft will encourage companies to develop more products to help people manage chronic diseases and conditions.

In addition to mobile apps, general wellness products may include exercise equipment, audio recordings, video games and other software. Products are not considered general wellness apps if they claim to treat or diagnose obesity, eating disorders, clinical anxiety, autism, muscle atrophy or erectile dysfunction, or if they restore a structure or function impaired due to a disease.

Products are also not considered low-risk if they are invasive, pose a safety risk when used without controls, as might lasers or

*(See* **Wellness**, *Page 2)*

**Wellness**, *from Page 1*

radiation, or raise questions about usability or biocompatibility. The draft includes a five-question algorithm that illustrates how the policy applies to specific products.

Comments on the draft are due April 16. View it at www.fdanews.com/01-19-16-wellness.pdf. — Elizabeth Orr

## COCIR Takes Issue With UDI, Incident Reports Under Proposed Device Regs

Important details on unique device identification, such as transition times, are missing from the EU's draft medical device regulation, a major industry group says.

More information is needed on who will administer the UDI system, what the transition times will be for various device classes and how many entities will assign UDIs, COCIR writes in updated comments on the proposal. If this information can't be included in the regulation, it should be clarified in the forthcoming delegated act, the group adds. COCIR represents radiological and electromedical equipment makers in the EU.

COCIR applauded Parliament's recommendation for a single EU-wide UDI system and database, as well as the European Commission's recommendation for a common UDI framework. "The core UDI features, including the label and data elements for the EU database, should be as interoperable as possible with what exists in the United States," the group says.

On clinical data and investigations, COCIR says the regulation appears to "incoherently borrow ideas" from the recently adopted Clinical Trials Regulation. The group argues that clinical trial requirements should be unique to devices, rather than mimic the pharmaceutical model.

The group also has reservations about a provision that would require devicemakers to submit trial results to an electronic database that would be made partially available to the public. Access to such information should be limited to professionals and there should be mechanisms to protect commercially sensitive information, the group adds.

And COCIR criticized a proposal put forth by Parliament that would require reporting of all adverse events meeting the MDR definition of "incident," calling it an "extreme and disproportionate expansion of the scope" of event reporting.

Adopting this provision would result in "a many hundredfold increase in the number of manufacturer reports to the electronic system," the vast majority of which would be routine corrective maintenance calls, COCIR maintains. The group recommends retaining the current requirement to report only serious incidents.

### CE Marking

COCIR said it supports efforts to strengthen the CE mark, but is concerned about proposals from the Commission and Parliament that would require additional premarket scrutiny of conformity assessments for the highest-risk devices.

"The proposals currently offered both add unnecessary delays to market for life-saving devices, and thereby risk seriously undermining patient safety, innovation and competitiveness," COCIR says. The group recommends instead that the Commission establish a process for devicemakers to get a scientific opinion from member state-vetted experts early in the development process for innovative devices. Notified Bodies could then consider this opinion during the conformity assessment.

Such a process could be a requirement for high-risk, innovative devices, with deviation from the opinion allowed only with acceptable justification, the group says.

COCIR also notes that the three-year transition period for complying with the regulations is acceptable only if it starts with the availability of implementing legislation.

View the updated comments at www.fdanews.com/01-15-15-COCIR.pdf. — April Hollis

## GUDID Accounts Now Available For Class II Implant Makers

Beginning Jan. 26, labelers of implantable, life-supporting and life-sustaining devices that are not Class III can register with the FDA's Global Unique Device Identification Database. Labelers of all other Class II devices will be able to request GUDID accounts later in 2015, the agency said Thursday.

Labelers of Class III devices and devices licensed under the Public Health Service Act have been able to sign up for GUDID accounts since September 2013, and the FDA has required Class III devices distributed in the U.S. to carry UDIs since Sept. 24, 2014.

Thursday's notice reminds companies to organize, connect and validate data before requesting a GUDID account or submitting device identifier data. That's because data that's live in the GUDID database cannot be corrected or amended.

The FDA is working with the National Library of Medicine to develop tools that will let the public access GUDID data. Search and download functions should be available this spring, the agency says.

The FDA has also updated two GUDID resources: HL7 SPL implementation files and GUDID Data Elements Reference Table.

The form to request a GUDID account is available at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416113.htm. — Elizabeth Orr

## J&J to Make Trial Data Public In Boost to Transparency

Johnson & Johnson plans to make clinical trial data on its devices and diagnostics available through an academic database, becoming the first devicemaker to take steps toward greater transparency of trial results.

Researchers will be able to seek data immediately via the Yale University Open Data Access project, which acts as an independent intermediary to manage requests and promote the use of trial information. All of the content of the database is de-identified, and YODA staff review and approve or deny researchers' requests to access it.

Johnson & Johnson's SmartTouch Catheter is set to be the first device for which trial data will be available through YODA, says Joseph Ross, a Yale assistant professor of medicine and the head of the YODA project. Ross adds that information about more trials will be made available as the devices are approved in the U.S. and EU.

### J&J to Include Trials From 2007

J&J spokesman Larry Thompson explained that YODA will eventually include products approved in 2014 and onward and data from trials beginning in 2007. This aligns with recent recommendations on data sharing by the Institute of Medicine, he notes (*see story, page 7*).

YODA launched in 2011 and, as of November, included information from 80 drug trials. J&J first partnered with the project in January 2014, when it announced plans to make available drug trial data gathered by its Janssen R&D unit. Thompson says it took several months for J&J and Yale to hammer out details of YODA governance and infrastructure. "Yale really did not begin accepting and reviewing clinical data requests until the last quarter of 2014," he adds.

Between October and the end of the year, YODA received eight complete data requests for Janssen information. Six of those have been approved and one researcher has already been granted access.

While J&J is the first devicemaker to have an ongoing partnership with YODA, Medtronic submitted trial data for its Infuse spinal cement product to the database in 2011. Researchers were able to use the information to show

*(See* **Transparency**, *Page 4)*

**Transparency**, *from Page 3*

that Infuse offered little or no benefit over alternatives.

Ross says Yale has spoken to other manufacturers about adding trial data to YODA, but has not yet reached any agreements. Still, "we are hopeful that other companies will join Johnson & Johnson and make their device trial data available to external investigators in the future," he says. — Elizabeth Orr

## FDA Approves Obesity Treatment Device, Requires Postmarket Study

The FDA approved a novel weight-loss treatment device despite its having missed a primary endpoint in a clinical trial, but ordered the sponsor, EnteroMedics, to conduct a five-year postmarket study to collect additional safety and effectiveness data.

The Maestro Rechargeable System is approved for adults who have a body mass index of 35 to 45 and at least one other obesity-related condition, such as type 2 diabetes, and who have not been able to shed extra pounds with a weight loss program.

In a clinical trial, patients implanted with the Maestro system lost 8.5 percent more excess weight than those in the control group after 12 months, but fell short of the trial's goal of at least 10 percent more weight loss.

However, an FDA advisory committee found the 18-month data supportive of sustained weight loss and agreed that the benefits of the device outweighed the risks for use in patients who met the criteria in the proposed indication.

The 100-patient postmarket study will look at Maestro's impact on weight loss and obesity-related conditions, adverse events and surgical revision and explant rates.

The Maestro system — a rechargeable electrical pulse generator, wire leads and electrodes implanted surgically into the abdomen — is the first weight-loss treatment device that targets the nerve pathway between the stomach and the brain that controls feelings of hunger and fullness, according to the FDA.

The therapy will be available this year on a limited basis at select bariatric centers of excellence and expand to other centers as reimbursement is secured, says EnteroMedics spokeswoman Eliza Schleifstein.

Now that the company has FDA approval, it can begin to convert the product's six Category III CPT codes to Category I codes, which are the reimbursement codes used to provide uniform coverage, Schleifstein says. In addition to seeking Medicare coverage, the company is negotiating with private insurers like Blue Cross & Blue Shield, she says.

Maestro is already CE-marked for the treatment of obesity and obesity with type 2 diabetes and is approved Australia, according to Schleifstein. — Jonathon Shacat

## 23andMe Back on Track With FDA, $60M Deal for Parkinson's Data

Direct-to-consumer genetics testing company 23andMe hopes to get its first FDA-cleared test on the market by the end of the year, company sources say.

The company stopped providing its online health-related analysis after a November 2013 FDA warning letter for providing diagnostic services without regulatory clearance. The agency also chided 23andMe's lack of progress on obtaining clearance despite regular communications with FDA officials over a four-year period.

The warning letter was closed out in March of last year, after the products were pulled from the market. In May, 23andMe submitted a 510(k) for a new test that detects Bloom syndrome, a rare disorder characterized by short stature, sensitivity to the sun and a predisposition to cancer.

*(See* **23andMe***, Page 5)*

**23andMe**, *from Page 4*

CEO Anne Wojcicki says the company has been working with the FDA on the submission and hopes to see that product approved by the end of this year. That could open the gateway to faster approval for all components of the company's tests, she adds.

The FDA declined to comment.

Separately, 23andMe has partnered with Genentech to develop a personalized treatment for Parkinson's disease. Under the agreement, 23andMe will share genomic sequencing data on about 3,000 Parkinson's customers in hopes of generating new therapeutic targets for the disease. The data set will be stripped of identifying information and include only customers who have agreed to participate in the research, 23andMe says.

22andMe will get $10 million up front for the information, plus as much as $50 million more if the project hits certain milestones. Deals with nine other large pharmaceutical and biotech companies are in the works, the firm says. — Elizabeth Orr

## MR Safety Credential Could Shield Firms From Liability

Makers of magnetic resonance imaging equipment could further protect themselves from wrongful death and injury lawsuits by helping to underwrite formal MR safety education, the head of a new credentialing organization says.

The American Board of Magnetic Resonance Safety, which announced its launch Jan. 12, offers three types of certification: magnetic resonance medical director/physician, magnetic resonance safety officer, and magnetic resonance safety expert. The group is the first to test and credential MRI users, rather than the equipment itself.

ABMRS Chairman and founder Emanuel Kanal, who directs MR services at the University of Pittsburgh Medical Center, says the current system does a good job of certifying and accrediting sites, but "no one out there … [is] certifying the humans and professionals overseeing the safety of the MR environment."

That has led to safety concerns. For example, some states require no certification whatsoever for MRI operators, and many MR sites have no formal pathways to address safety concerns. Meanwhile, federal anti-kickback laws mean that physicians who want MRI testing performed must leave the actual ordering and interpretation of results to a radiologist, who may not know, for instance, if the patient is contraindicated for a contrast agent.

As a result, nearly all MRI injuries that occur during scans are the result of human error and could be prevented with proper training and implementation of safe practice guidelines, Kanal says. And while injuries rarely stem from equipment failures, MRI manufacturers are typically named when an injured patient files suit, he says.

Kanal recommends that companies consider funding MR safety training for purchasers of MRI systems, as one company he knows of has recently agreed to do. That would serve to protect patients while also strengthening the manufacturer's liability shield in court, he says.

ABMRS is still finalizing the examinations themselves as well as the details of the certification program, but plans to begin offering the MRMD and MRSO tests as early as June. The MRSE test will fire later in 2015.

Board members include Terry Woods, the FDA's MR safety expert, and David Grainger, a senior device specialist at the UK's Medicines and Healthcare products Regulatory Agency.
— Elizabeth Orr

## Philips Subsidiary Warned By FDA Over MDR Failures

Respironics California, a Philips subsidiary, recieved an FDA warning letter for medical device reporting failures, including one related to a life-sustaining/life-supporting device.

The company did not submit an MDR for a complaint referencing a malfunction of a life-sustaining/life-supporting device, according to

*(See* **Respironics**, *Page 6)*

**Respironics**, *from Page 5*

the Nov. 17 letter posted recently online. Other MDRs were submitted to the FDA beyond the 30-day timeframe.

The Carlsbad, Calif., company makes mechanical ventilators and provides services for certain discontinued mechanical ventilators.

The investigator also notes that reports did not rule out the possibility that the referenced malfunctions might cause or contribute to a death or serious injury if they recurred. The warning letter follows an April 4 through May 8, 2014, inspection by the FDA's Los Angeles district office.

Respironics also failed to document in an MDR that it made several attempts to gather patient information, the date of an event and the device serial number.

The letter further notes that although Respironics became aware of a reportable malfunction in July 2013 and learned the results of its investigation for the returned device in November of that year, the FDA did not receive a supplemental MDR with this information in the required one-month timeframe.

Respironics did not respond to a request for comment by press time. The warning letter is available at www.fdanews.com/01-13-15-Respironics.pdf. — April Hollis

## Industry Welcomes Deregulation of Hundreds of Devices in Mexico

Industry groups say the recent deregulation of 573 low-risk devices by Mexico's regulatory body, COFEPRIS, is both extremely positive for the sector and a major effort to improve access to life-saving and life-enhancing medical technology in the country.

U.S.-based AdvaMed and the Mexican Association of Innovative Medical Device Industries say it is essential that the agency establish a flexible mechanism to continually update the list, given the constant evolution of medical technology.

Both groups say the level of dialogue and collaboration between industry and COFEPRIS staff has been improving in recent years and they are eager to build on that progress. At the same time, they say devicemakers face major challenges this year, including a second wave of device registration extensions.

According to AMID, the number of procedures slated for extensions from late 2014 to 2016 is higher than the total number of transactions entered to date. The group has met with COFEPRIS to identify the best way to efficiently manage the additional workload.

The recent deregulation of many devices was the result of joint efforts by COFEPRIS, industry associations in the region, Mexico's commerce ministry

*(See* **Mexico**, *Page 7)*

**Mexico**, *from Page 6*

and the U.S. Embassy in Mexico. The agency determined that the safety and efficacy of the products, which include diagnostic agents and dental treatment materials and supplies, is well established and supported by technical and scientific information (*IDDM*, Jan. 9). — Jonathon Shacat

## IOM: Industry, Regulators Must Plan for Trial Data Sharing

The Institute of Medicine is calling on clinical trial sponsors and governments to develop plans for substantially greater sharing of clinical trial data.

In a report containing sweeping recommendations for both industry and regulators, the IOM calls on governments to create guidance for industry that mandates data sharing and to establish the technologies and standardized data formats to facilitate it.

### Datasets Should Not Include Private Info

In addition, regulators should develop datasets that do not contain confidential information so that they can be more readily shared, the report says. The goal should be to make data for approved studies of all products available to the public no more than 30 days after regulatory action or 18 months after completion of studies.

Sponsors, IOM says, need to commit to data sharing by removing confidential information from clinical trials reports and developing data plans at the outset of studies that address how and when data will be distributed.

The data sharing plans should address how data will be shared in compliance with all international privacy laws and that information should be incorporated into informed consent documents.

The IOM recommendations were developed by a panel comprised of representatives from medical societies, universities, the FDA and Johnson & Johnson, which has been partnering with Yale University to share both device and drug trial data (*see story, page 3*).

The report was sponsored by 19 companies, the FDA, National Institutes of Health, the UK's Medical Research Council and the Doris Duke Charitable Foundation with the aim of developing a consensus on data sharing concerns.

Get the report at http://iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx. — Lena Freund

## EU Panel Urges Rigorous Assessment Of Risks of Nanomaterials in Devices

Risk assessments of nanomaterials used in medical devices must be performed on a case-by-case basis since the properties of nanoparticles cannot be extrapolated from one to another, a European Commission expert group says.

Manufacturers should begin by preparing a physicochemical characterization of the nanomaterials and then categorize the device as invasive or noninvasive before assessing possible exposure routes. The devicemaker should then check whether systemic exposure is possible. If it is not, possible local effects should be considered, the Scientific Committee on Emerging and Newly Identified Health Risks says.

If either physical or local effects are possible and the materials fit the on the nanoscale, companies should conduct a hazard assessment and dose response characterization before moving on to a thorough risk assessment. Tables in the opinion show what amounts of nanomaterials may pose an exposure risk.

SCENIHR defines nanomaterials as any particulate substances with at least one dimension in the size range between 1 nm and 100 nm. Examples of nanomaterials in devices include iron oxide or gold nanomaterials used as heat therapy against cancer and nanosilver used as an antibacterial agent in wound dressings.

The final opinion on nanomaterials in medical devices includes tables showing what amounts of nanomaterials may pose an exposure risk and a flowchart for identifying and characterizing them.

*(See* **SCENIHR**, *Page 8)*

**SCENIHR**, *from Page 7*

Parameters to consider in characterizing nanomaterials include chemical composition, particle size, physical form, particle concentration, surface area, surface chemistry, pH, viscosity and seven additional factors. Common techniques for characterizing nanoparticles include atomic force microscopy, x-ray diffraction, small-angle x-ray scattering, dynamic light scattering, nanoparticle tracking analysis and various electron microscopy techniques, SCENIHR says.

The opinion follows a proposed recast of EU device regulations that includes a definition of nanomaterial and provisions on risk classification, labeling and instructions for use for products that contain them. Under the proposal, devices with nanomaterials would be regulated as Class III "highest-risk" devices.

View the guidance at www.fdanews.com/01-19-15-nano.pdf. — Elizabeth Orr

## 2014 A Good Year for Investment, Buoyed by Intarcia, Invitae Deals

Startups focused on a diabetes treatment device and novel genetic testing were among the biggest winners of venture capital in 2014, new analysis from venture capital tracker CB Insights shows.

Boston-based Intarcia Therapeutics raised $200 million in a growth equity round, making it the largest venture capital bet in the devices sector and second only to drug company Moderna in healthcare overall. Intarcia is developing the ITCA 650, a matchstick-sized pump that continuously delivers the glucose-replacement drug exenatide for patients with Type 2 diabetes. The device, which requires replacement just once or twice a year, performed well in Phase 3 trials, the company announced in October.

The other company to make the top 10 in terms of venture capital winnings was Invitae, a San Francisco-based company offering direct-to-consumer genetic tests. Invitae's single diagnostic test can detect a variety of genetic disorders related to cancer and cardiovascular, blood, neurologic and developmental problems. With $120 million from a Series F venture capital round, Invitae plans to go public this spring.

In all, medtech companies accounted for 34 percent of the 537 healthcare companies funded via venture capital last year, marking the second year that devices garnered the most deals in the sector. Biotechnology comprised 25 percent of overall deals, while medical equipment and supplies drew 2 percent. One percent of funding rounds went to dental products companies.

The number of healthcare funding rounds for 2014 was essentially flat, compared with 2013 when 550 companies were funded. However, total dollar value jumped from $6.4 billion in 2013 to $8.2 billion last year.

View the CB Insights report at www.cbinsights.com/venture-capital-2014. — Elizabeth Orr

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# MEDICAL DEVICE COMPLAINT MANAGEMENT | Building a Robust System to Meet Global Requirements

PRESENTED BY OMBU ENTERPRISES AND FDANEWS

FEB. 25-26, 2015 | WYNDHAM BEACON HILL, BOSTON, MA

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**—Shivani Persad, Associate Complaint Coordinator, Fresenius Medical Care**

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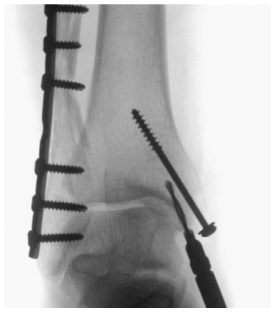
- Understanding why the source of a complaint (Facebook, Twitter, email, phone call) is not your chief concern — it's how to handle the communication
- The proper use of corrective action in complaint management, including statistical analysis
- Developing a complaint classification system that links to the risk management file
- Analysis methods to help determine the impact of design changes on regulatory requirements
- How to distinguish between enhancements and recalls, following the FDA guidance.
- Recall requirements in the US, EU, and Canada.





## Day 1

**WEDNESDAY, FEB. 25, 2014**

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

9:00 a.m. – 10:15 a.m.

### Part A – The Intersection of Complaints and the Regulatory Structure

- Understanding the Quality Management System (QMS) in the US, EU, and Canada
- Distinguishing records and reports to regulatory agencies (content, trigger, and timing)
- How and why the FDA conducts inspections and the guiding documents they use
  - Quality System Inspection Technique
  - Compliance Program 7382.845 Inspection of Medical Device Manufacturers
- Using sampling plans as part of the Medical Device Directive (MDD) audit

**Exercise – FDA Inspection Levels**
**Exercise – QSIT sampling plans for records**

10:15 a.m. – 10:30 a.m. | **BREAK**

10:30 a.m. – 12:00 p.m.

### Part B – How Newly Enacted Unique Device Identification Will Impact Complaints

- Overview of the US regulations regarding UDI
- What are Device Identifiers and Production Identifiers — and how do they differ
- Understanding the GUDID and the information you need to supply

**Exercise – Creating a new Device Identifier**

### Part C – Servicing: The Front Line for Complaints?

- Definition of servicing — is your definition and regulators' the same?
- How servicing relates to other QMS elements?
- Producing service records and linking them to complaints
- Tips, tools, and techniques for analyzing service records; what should you be looking for?

**Exercise – Analyze a small set of service records using quality tools**

12:00 p.m. – 1:00 pm | **LUNCH BREAK**

1:00 p.m. – 2:30 p.m.

### Part D – Complaints

- Definition of a complaint —distinguishing regulatory complaints from customer service complaints
- Comparing and contrasting QSR vs. ISO 13485 definitions
- Successfully developing and managing complaint classification systems
- Fully understanding complaint system interrelationships, it's harder than it appears

**Complaints and corrective action**
- Complaints and MDRs
- Complaints and EU Vigilance
- Complaints and risk management (ISO 14971:2007)

- Complaint system flowchart
- Determining the required content for complaint records

**Exercise – Analyze customer reports to determine if they are a complaint and potentially reportable**

2:30 p.m. – 2:45 p.m. | **BREAK**

2:45 p.m. – 4:30 p.m.

### Part E – Medical Device Reports (US)

- Understanding the criteria for reporting
- Establishing the MDR event files that serve their purpose and stand up to FDA scrutiny
- Identifying Designated Individuals
- MDR system interrelationships
- Examining the nexus between MDRs and complaints
- Getting to know the types of MDRs (30 day and 5 day)
- Reporting MDRs — paper or electronic
- Records required for the MDR system — what you must have

**Exercise – Initiate a Medical Device Report**

### Part F – Medical Device Reports in the EU and Canada

- Understanding the criteria for reporting
- The regulatory structure in the EU (MDD and MedDev)
- The regulatory structure in Canada
- Role of the Notified Body in the

Vigilance System

- Role of the MDD Authorized Representative in the Vigilance System

**Exercise – Analyze an adverse event to determine when to report**

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

## Day 2

**THURSDAY, FEB. 26, 2014**

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

**9:00 a.m. – 10:15 a.m.**

### Part G – Corrective Action and Preventive Action (CA&PA)

- The difference between corrective action (CA) and preventive action (PA)
- Understanding CA&PA interrelationships in the QMS
- The CA&PA flowchart —implementing it in your QMS
  - CA&PA verification and validation
  - CA&PA effectiveness review
  - CA&PA records — opening, closing and managing the records effectively
- Tips, tools and techniques for complaint analysis; what should you be looking for?

**Exercise – Analyze complaints as quality data to identify quality problems**

**10:15 a.m. – 10:30 a.m. | BREAK**

**10:30 a.m. – 12:00 p.m.**

### Part H – Design Changes

- Understand the role of change in the design control system
- Design change interrelationships —the five important considerations
  - When a production change is a design change
  - Does the design change create a new Device Identifier?
  - Does the design change require an updated 510(k)?
  - Does the design change impact the Risk Management File?
  - Is the design change an enhancement or a recall?
- The design change flow chart shows the picture
- Design change records —tips for maintaining the Design History File (DHF)

**Exercise – Classify changes as a design change or a production process change**

**12:00 p.m. – 1:00 pm | LUNCH BREAK**

**1:00 p.m. – 2:30 p.m.**

### Part I – 510(k) Changes

- When a design change requires a pre-market notification change
- 510(k) change process interrelationships
- 510(k) change records and reports
- FDA's 1997 guidance document — 17 years old, but still applicable today
- The 2012 law and FDA's plan — what's the latest and what's on the horizon

**Exercise – Analyze design changes to determine if they require a revised 510(k)**

**2:30 p.m. – 2:45 p.m. | BREAK**

**2:45 p.m. – 4:30 p.m.**

### Part J – Corrections and Removals (C&R)

- Defining the terms — a source of constant confusion
- Understanding how the C&R regulations relate to the QMS
- Distinguishing enhancements from recalls – the FDA guidance and its theory
- C&R records and reports — distinguishing between the requirements
- Overview of the integrated system and how to make it work for you
- Bringing all the pieces together — best practices for building C&R procedures that work
- The link between C&R reports and recalls
- Recalls caused by suppliers

**Exercise – Evaluate proposed field actions to determine if they are a correction or a removal**

**4:30 p.m. | ADJOURN WORKSHOP**

*It was a very methodical approach, enjoyed the examples."*

**—Randall Lenz, CQT Consultant / QE, Stryker Instruments**

# a Robust System to Meet Global Requirements

## 11 Comprehensive Exercises You Can't Afford to Miss!

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1. **FDA Inspection Level —** FDA investigators plan the extent of their inspections based on the levels in the Program Compliance Guide. This exercise provides participants an opportunity to apply these ideas and understand the factors that determine the depth of the inspection.

2. **QSIT Sampling Plans for Records —** When an FDA investigator asks for records, the number reviewed is determined by a sampling plan in QSIT. This exercise explains how the investigator classifies the records and estimates the error rate. It is not Z1.4 acceptance sampling.

3. **Creating a New Device Identifier —** The UDI regulations require manufacturers to create Device Identifiers (DI) for each version or model as well as Device Identifiers for each packing level. They must be included in the complaint records, Medical Device Reports, and Correction & Removal files. This exercise helps participants understand when a change creates a new Device Identifier (DI).

4. **Analyze a Small Set of Service Records Using Quality Tools —** 820.200 requires manufacturers to analyze service records using statistical techniques applicable for data analysis in 820.100. In some cases, servicing, complaints and MDRs are tightly coupled. This exercise introduces a small data set and gives participants an opportunity to apply techniques.

5. **Analyze Customer Reports to Determine If They Are a Complaint and Potentially Reportable —** The definition of complaint in medical device regulations is technical, and requires analysis to determine when a report alleges a "regulatory complaint". In addition, complaints must be evaluated to determine which ones could lead to a Medical Device Report. This exercise provides examples that help participants distinguish among the various cases.

6. **Initiate a Medical Device Report —** In the US, some complaints are reported to the FDA as a Medical Device Report. This exercise uses an example problem and offers participants an opportunity to see how the information relates to the fields in the MDR form.

7. **Analyze an Adverse Event to Determine When to Report —** In the EU, some are reported using the Manufacturer's Incident Report form from MEDDEV 12.2-1 on the Vigilance System. This exercise uses an example problem and offers participants an opportunity to see how the information relates to the fields in the MDR form.

8. **Analyze Complaints as Quality Data to Identify Quality Problems —** Medical device manufacturers expect to receive complaints at some rate. The manufacturer must track the rate for different kinds of complaints, for risk management post-market surveillance and for EU vigilance reporting. This exercise provides an opportunity for participants to determine a baseline rate, a trigger point, and determine if the rate is still acceptable.

9. **Classify Changes as a Design Change or a Production Process Change —** QSIT informs the FDA investigator that Production and Process Changes could be Design Changes. This exercise provides participants an opportunity to classify changes and provides insight into the decisions to make in the QMS.

10. **Analyze Design Changes to Determine If They Require a 510(K) —** Every design change for a 510(k) device must be evaluated to determine if it is significant enough to update the 510(k). This exercise provides some situations for participants to analyze.

11. **Evaluate Proposed Field Actions to Determine If They Are a Correction or a Removal —** Whenever a manufacturer changes a product in the field, there must be an evaluation to determine if the change is a correction or a removal. In addition, there must be an evaluation of reportablility. This exercise provides practice in making those evaluations.

## ABOUT YOUR INSTRUCTOR

**Dan O'Leary**

Dan O'Leary is President of Ombu Enterprises, LLC, an education, training and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management. Dan has more than 30 year's experience in quality, operations and program management in regulated industries, including aviation, defense, medical devices, and clinical labs. He holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer and Six Sigma Black Belt; and is certified by APICS in Resource Management.

**Ombu Enterprises, LLC**

Ombu works with manufacturing companies, offering training and execution in operational excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

*"Very informative and could pull documentation in support of information provided. I have high confidence in the information he provided. Great up to date information. I liked asking specific questions and getting his opinions."*

**—Linda Todd, Sr. Post Market Surveillance Analyst, Spectranetics**

*"Dan is a wealth of knowledge in regards to all aspects of medical device regulations."*

**— Kanan Bhavsar, PV Clinical Trial and Drug Safety Specialist, Merck**

## COURSE BINDER MATERIALS

- Full slides from the PowerPoint presentations
- A copy of each interactive exercise worksheet as well as answer keys
- An annotated version of MDR sections regulation based on recent Warning Letters
- An Excel worksheet that helps analyze the FDA regulations. It has a series of questions that start with a complaint and follow the reporting and record keeping decisions to help understand the integrated requirements spread across different parts of the regulations.
- Reference documents:
  - FDA guidance on Medical Device Reporting
  - FDA draft guidance on Medical Device Reporting
  - Comparison of MDR Rule Changes
  - FDA guidance on Enhancements and Recalls
  - Comparison Part 7 and Part 806 definitions
  - FDA guidance document on 510(k) changes
  - MEDDEV document on the Vigilance System
  - Health Canada document on Medical Device Problem Reporting

## WHO SHOULD ATTEND

- Quality Managers
- Regulatory Affairs Managers
- Engineering Managers
- Quality Engineers
- Design Engineers
- Project Managers involved in design and development
- Specialists assigned to complaints, corrective actions or medical device reporting
- Recall coordinators
- Medical staff evaluating risk, safety or effectiveness
- General/corporate counsel

*The materials are excellent and a great handout to be used in any organization. Dan really put a lot of work into the materials and workshop."*

**— Cheryl Landrum, Quality Analyst, Kimberly Clark**

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