INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

First MDSAP Alum Gives Single Audit Process High Marks; Challenge Was Brazilian, Aussie Regs

Manufacturers planning to participate in the Medical Device Single Audit Program should first study up on Australian and Brazilian regulations, an official at the first company to go through a MDSAP audit tells *IDDM*.

James Hamer, global director of quality and regulatory affairs at Arthrex, says the company became interested in the International Medical Device Regulators Forum's two-year MDSAP pilot program after participating in a U.S. FDA pilot program. The North Naples, Fla., manufacturer of orthopedic surgical supplies was able to defer routine FDA audits by annually submitting ISO audit results to the agency.

"We saw this as a huge benefit in that … audits and inspections can be a huge resource drain," Hamer explains. When company officials heard about the MDSAP audits, which would allow Arthrex to similarly "set aside" audits by Brazil, Canada, Australia and Japan, it was easy to opt for the audit and obtain management buy-in, he says.

Scheduling Challenges

Making the choice to participate was easy, but scheduling the audit posed a hurdle, Hamer says. When the company decided to participate in MDSAP in late July 2014, it already had an ISO audit scheduled for September. Auditor BSI worked with the FDA and Health Canada to coordinate the timing and contractual details, and the audit took place from Sept. 22-26, 2014, with four BSI inspectors and U.S. and Canadian regulatory observers.

The MDSAP auditors' approach followed the FDA's Quality Systems Inspection Technique model more closely than a standard notified body approach, Hamer says. But the audit touched all areas of 21 CFR 820, ISO 13485 and additional Brazilian and Australian regulatory requirements. The most striking difference from an FDA audit was that, in Hamer's experience, FDA investigators tend to look to complaints as a basis for further investigation, while the MDSAP team balanced complaints, CAPA and nonconformances.

(See **Arthex***, Page 2)*

Arthex, *from Page 1*

The largest surprise during the audit was questions on fine details of Australian and Brazilian regulations, Hamer says. "The MDSAP audit team was understanding in how they could have gone unnoticed," he relates, "but still wrote nonconformities."

The company will stick with MDSAP audits in the future, Hamer says.

Arthrex and other devicemakers that have gone through MDSAP audits will be able to share their experiences during a June 23 IMDRF meeting set to coincide with the midpoint of the pilot program (*IDDM*, March 20). — Elizabeth Orr

Task Force Urges Sweeping Reforms To Bolster Indian Device Sector

A public-private task force in India is urging the government to purchase Indian-made medical devices when possible to boost growth in the domestic medtech industry.

To support newer companies, the Task Force on the Medical Devices Sector in India also recommends that the government relax rules encouraging only firms that have been in business for at least three to five years to bid on government contracts. Preference also should be given to devices made by smaller companies, says a report released by the group this week.

Pricing for devices should be regulated separately from drugs and would be based more strongly on return on investment for manufacturers, the task force suggests. This would allow the government to consider the costs of a complete "basket" of devices associated with a single procedure, a move that would help to keep the industry viable. The group also calls for tax and duty reforms, including discounts on import duties, restrictions on the import of second-hand diagnostic tools and promotion of medical device exports.

These new policies should be supported by an independent facilitating body devoted to the medical device sector, the report says. This body would create benchmarks based on international best practices, develop public-private knowledge networks, and identify and prevent technical barriers to trade. In addition, the Department of Pharmaceuticals should be strengthened and renamed the Department of Pharmaceuticals and Medical Devices, the task force advises.

The report also calls for the government to build infrastructure to support medical device parks with common medical device testing facilities that would be funded at least partially by industry. One such park is already planned for Chennai.

To speed technological upgrades, the government should create a system that would allow device companies to exchange intellectual property, the task force adds. Incubation centers should be established and more government seed money provided for start-ups, the group adds.

Part of Make in India

The secretary of the Department of Pharmaceuticals established the task force last fall to bolster Prime Minister Narendra Modi's Make in India campaign. The group sought input from government, industry and consulting groups before issuing its recommendations.

Rajiv Nath, forum coordinator of device industry group AIMED praised the task force's report. "It sets a clear and definite road map for creation of a vibrant ecosystem for manufacturing of medical devices in the country," he tells *IDDM*. If the recommendations are implemented quickly and thoroughly, they could allow India to end its dependence on device imports in just a few years, he adds.

Recommendations concerning financial support to manufacturing units, reversal of inverted duty structure, an MRP-based taxation system, creation of a separate department and separate law book for medical devices were of particular significance, Nath says. Still, additional measures — such as higher duties on imported finished goods — may be needed to fully encourage the sector, he adds.

View the report at www.fdanews.com/04-20-15-taskforce.pdf. — Elizabeth Orr

FTC Bars App's Melanoma Detection Claims; Fine Assessed

Health Discovery Corp. may not make any misleading claims about an app purported to diagnose skin cancer, the U.S. Federal Trade Commission says in a final consent order issued April 13.

The consent order follows a February complaint and subsequent comment period. In the complaint, the FTC said there was no scientific data supporting the company's claim that its MelApp product can evaluate moles for melanoma symptoms (*IDDM*, Feb. 27).

To use the app, customers would photograph the mole on a mobile phone and input other information about it, and the app would categorize the mole as low, medium or high risk for skin cancer. Health Discovery claimed the app's analysis was accurate and scientifically proven. The FTC, which regulates advertising, says it was not.

The consent order bars the company from claiming its device detects or diagnoses melanoma or its risk factors, unless the statement is supported by scientific evidence. While inspired by MelApp, the wording of the consent order would apply to any device manufactured by Health Discovery. Health Discovery will also pay $17,963 in penalties for violating the FTC Act.

In addition, Health Discovery must maintain all materials related to the consent order for five years and provide them to the FTC upon request. This may include advertising, scientific tests or demonstrations and acknowledgements of the receipt of the order. Health Discovery must report to the commission on its compliance within 60 days.

The commission voted 4-1 to approve the final consent order, with Commissioner Maureen Ohlhausen voting no. Ohlhausen says the regulatory crackdown could have a chilling effect on other medical app makers.

Regulation of mobile apps by the U.S. FDA is still developing, and spokesman Christopher Kelly declined to comment on Health Discovery specifically. However, he notes that unless otherwise ageed to in specific cases the FTC is in charge of regulation of the truth or falsity of advertising, while the FDA has primary jurisdiction over labeling.

View the final order at www.fdanews.com/04-20-15-melapp.pdf.
— Elizabeth Orr

Malaysia Offers More Details On Fast Track Registration

With a June 30 device registration deadline fast approaching, Malaysia's Medical Device Authority has released more guidance for manufacturers working to list their products.

Malaysia is in the process of implementing its first comprehensive medical device regulations, which require registration of all devices distributed in the country (*IDDM*, March 20). Fast track registration is available through June 30 for devices that already have been approved for marketing in the U.S., EU, Canada, Japan or Australia. Devices that have been registered in other countries may be eligible if they meet additional conditions, as may sterile Class A devices with measuring functions.

Once products are registered, manufacturers have until July 1, 2020 to obtain a conformity assessment. However, firms must appoint a conformity assessment body to conduct the review by July 1, 2018.

The MDA may revoke registration if a device is reported to be unsafe or the manufacturer doesn't pursue a conformity assessment. Registrations may also be put on hold if safety events requiring corrective action occur during the registration process.

The details were included in a notice issued April 6. View it at www.fdanews.com/04-20-15-malaysia.pdf. — Elizabeth Orr

Contact Lens Maker Gets Warning Letter For GMP, CAPA Violations

A contact lens manufacturer that failed to respond to a Form 483 in February following an FDA inspection now must respond to a warning letter.

The letter, posted April 3, says Visionary Contact Lens of Anaheim, Calif., violated established protocol by not adequately validating software for its intended use. It cites Visionary's failure to validate its CNC Lathe software, used in manufacturing, and the MAS 90 software used in labeling.

The FDA challenges Visionary for not ensuring that all of its manufacturing equipment met specified requirements and was appropriately placed and installed.

Additionally, verification and validation was deficient in the company's corrective and preventive action procedures. The company didn't investigate the cause of nonconforming products and other quality problems, the letter says.

Visionary also didn't identify actions needed to correct these problems. FDA points to nonconformance reports from December 2014 and January 2015, saying the reports lacked evidence an investigation was done or corrective action was implemented.

The FDA goes on to say that Visionary failed to conduct quality audits from 2011 through 2014 and, according to several records, failed to train employees in GMP, CAPA and other procedures to ensure quality.

The devicemaker is making corrections to ensure there will be no recurrence, a spokesman tells *IDDM*.

The FDA asks that manufacturers respond to Form 483s within 15 business days and address each observation with either a timeline for correction or a request for further clarification on what action should be taken. The responses are not formally required, but often help prevent warning letters like the one issued to Visionary.

Read the FDA letter at www.fdanews.com/04-15-15-Visionary.pdf. — Charlotte Astor

CAPA, Complaint Handling Bring Warning Letter to Stanmore

Stanmore Implants Worldwide, a manufacturer of extendable femur and knee-replacement devices, received an FDA warning letter for corrective and preventive action, complaint handling and auditing violations.

The Nov. 26 letter to the UK-based devicemaker says Stanmore's CAPA procedures do not ensure that information is received by appropriate personnel.

The investigator also dinged the company's corrective action procedures for not requiring documentation of CAPA activities. Investigators found a CAPA file closed as effective without confirming any corrective actions had been completed.

Another file, on corrective action to change plastic components related to the company's ITAP prosthesis, did not contain adequate validation of the corrective action, the investigator found.

The FDA also criticizes the company's complaint handling procedures, citing failure to evaluate complaints for MDR reportability, failure to document oral complaints upon receipt and failure to process complaints in a consistent and timely manner.

Further, the complaint handling procedure does not require that records of investigation include the nature of the complaint, device name and control number, or dates and results of the investigation, the letter says.

The FDA also rapped Stanmore's quality audit system. According to the warning letter, the company violated a rule that auditors must not have responsibility for areas they audited in 2012 and 2013.

The FDA says that while Stanmore had revised these procedures since the July 2014 inspection, it remains unclear if personnel were trained in the new procedures and whether a retrospective review of complaints had been conducted.

The company did not respond to requests for comment. Read the letter at www.fdanews.com/04-14-15-Stanmore.pdf. — Charlotte Astor

Fluoroscope Regulation Word Change Will Not Affect Manufacturers

Changing one word in an FDA regulation affecting fluoroscope equipment will have no effect on devicemakers, a trade group official says.

On Monday, FDA published a direct final rule amending its 13-year-old standard for fluoroscope equipment by changing "any linear dimension" to "every linear dimension." The FDA also used "any linear dimension" in another rule in the original standard which could have caused confusion. The language is not changed in this section.

Thad Flood, industry director for the Medical Imaging & Technology Alliance, confirmed that the change clears up a potential language issue.

The FDA also published a companion proposal to provide a framework to finalize a new rule. Public comment will be accepted through June 29. Read the proposal at www.fdanews.com/04-14-15-Proposal.pdf. Read the rule at www.fdanews.com/04-14-15-Rule.pdf. — Charlotte Astor

J&J Device Sales Drop 11.4%, 1Q Earnings Report Shows

Johnson & Johnson's device revenues dropped by more than 11 percent in the most recent quarter, the New Brunswick, N.J.-based health care giant reported Tuesday.

Financial records show J&J's worldwide device sales for the first quarter of 2015 totaled $6.3 billion, down 11.4 percent from the same quarter in 2014. Domestic sales were down by 6.1 percent, while international sales decreased 15.6 percent.

Much of the drop was caused by acquisitions, sales and negative currency trends, J&J says. If those are removed from consideration, domestic sales increased by 1.1 percent and international sales increased by 1.5 percent. Sales of electrophysiology, orthopedic, endocutter and insulin delivery products were particularly strong, while vision care sales dropped because of changing buying patterns and market competition.

*(See **J&J**, Page 6)*

J&J, *from Page 5*

J&J remains optimistic about the future of its device division, CFO Dominic Caruso says. The company recently exited the women's health business and has about 30 new products to launch through the end of 2016. Caruso also foresees a stronger future for its BioSense Webster cardiological products.

"We are pleased with being in the cardiovascular device space where innovation is rewarded and where there is significant unmet need that we can actually address," he says. By contrast, the company's recently sold Cordis division was more of a "commodity business" that will be better-served by new owners Cardinal Health. The $1.9 billion sale was announced last quarter.

A priority for the company going forward will be collaborating with Google Life Sciences to advance development of a surgical robotics program, says Louise Mehrota, vice president of investor relations.

The company spent $139 million during the quarter to resolve class action cases related to failed metal-on-metal hips made by subsidiary DePuy. In addition, J&J sold its Ortho-Clinical Diagnostics group for $26 million.

J&J's overall earnings for the quarter were down 4.1 percent to $17.4 billion.
— Elizabeth Orr

FDA Seeks Participants for Pilot Home Use Device Labeling Database

The U.S. FDA's Center for Devices and Radiological Health is launching a public database of labeling for home use devices and is looking for devicemakers to help test it later this year.

The goal of the CDRH Home Use Labeling Pilot program is to improve the safety of medical devices that are used in the home, the FDA says, noting that people may lack specific training in use of a device and are more dependent on the labeling and package inserts than medical professionals. Moreover, if the device is used over a period of years, the original labeling may be lost or not reflect updates to safety information and instructions for use.

Some manufacturers address this concern by putting safety information on their websites, the FDA acknowledges. Those sites often focus on newer products and don't include information on older models or products no longer being sold. Further, most manufacturers don't post all labeling and package inserts for every device they have listed, the agency says.

The CDRH database will include information on labels and package inserts for all home-use devices. Consumers will be able to access the database through the FDA website and search for information on specific devices.

During the pilot, participants will be asked to test the electronic submissions process and practice submitting labels and package inserts in PDF format. Company feedback will be used to evaluate the database. Submitted packaging and

(See **Home Use**, *Page 7)*

Home Use, *from Page 7*

labeling will not be evaluated for potential regulatory concerns and the database will be private during the trial, the FDA says.

Companies interested in participating in the project may apply throughout the month of May. The program will run from July 1 through Dec. 31.

For information, contact Mary.Brady@fda.hhs.gov. No more than nine manufacturers will be asked to participate.

View the announcement at www.fdanews.com/04-20-15-homeuse.pdf. — Elizabeth Orr

FDA, CMS Form Task Force To Coordinate LDT Regulation

The Centers for Medicare & Medicaid Services and U.S. FDA are establishing an interagency task force to address issues around the regulation of laboratory-developed tests, including LDT quality requirements.

Leaders and subject matter experts from both agencies will identify areas of overlap and work to clarify responsibilities, minimize duplication and maximize efficiency, the FDA and CMS said Thursday. The task force will also clarify terminology each agency uses to ensure that laboratories understand what is expected of them and offer stakeholder education, including an upcoming webinar series on LDTs.

The FDA proposed a risk-based regulatory framework for LDTs in October that establishes registration, approval and reporting requirements for the tests. The agency is currently reviewing comments from stakeholders and could modify its final guidance to reflect concerns about the draft (*IDDM*, Feb. 6).

Once the FDA framework takes effect, the agency will be responsible for LDTs themselves, but CMS will retain oversight of the laboratories under the provisions of the Clinical Laboratory Improvement Act. This includes overseeing laboratory operations and qualifications of laboratory staff.

The group will have about 20 members and plans to meet for "many months," says FDA spokeswoman Jennifer Dooren.

AdvaMed called the task force a positive step. Stakeholders have been confused as to how the two agencies will divvy up responsibilities related to LDT oversight. Historically, CMS has regulated LDTs via its CLIA authority, but FDA has said growing use and increasing complexity of these tests warrants stricter regulation.

Stakeholders who have thoughts about the task force should contact the FDA at LDT-Framework@FDA.hhs.gov. — Elizabeth Orr

Japan Extends Third-Party High-Risk Device Certification

Japan's medical device authority has expanded its conformity assessment certification system to allow private third-party bodies to certify that certain higher-risk specially controlled devices conform to standards.

In an effort to expedite patient access to new products, the Pharmaceutical and Medical Devices Agency has accredited 12 third-party organizations to conduct the certifications, eliminating the need for the products to obtain approval from the health minister.

Previously, devicemakers could only get third-party certification for lower-risk devices, such as ultrasonic diagnostic equipment and dental alloys. The revised regulation extends the range of third-party certification to higher-risk specially controlled devices, such as pen-type insulin injectors and blood filters for heparin-coated cardiopulmonary bypass circuits, according to information the PMDA released last week.

The Japanese government carved out a new category for medical devices in a November 2013 amendment to the Pharmaceutical Affairs Law. *The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* took effect a year later on Nov. 25, 2014.

Read an outline of the revision at www.fdanews.com/04-15-Japan-Revisions.pdf. — Jonathon Shacat

IN BRIEF

Patch Targets Peanut Allergy

The FDA has awarded breakthrough therapy designation to DBV Technologies' peanut allergy treatment Viaskin Peanut, marking the first time the agency has granted the designation for a food allergy, the France-based company says.

Using a technique that delivers an allergen directly to the skin's outer layers to stimulate the immune system, Viaskin's electrostatic patch targets antigen-presenting cells without letting antigen seep into the bloodstream, the company says.

In a Phase IIb trial, children who used Viaskin Peanut responded positively and significantly to 250 micrograms of the treatment, DBV says, adding the product's clinical safety profile was also strong across all age groups. The company, which plans to conduct a Phase III trial of Viaskin Peanut, is also developing treatments for milk and dust mite allergies.

Former Ethicon Execs Indicted

The Department of Justice has charged two former Acclarent officials with conspiracy and fraud, citing an alleged off-label marketing scheme for a sinus device.

DOJ accused former CEO William Facteau and Patrick Fabian, former vice president of sales, of speeding the development and sale of the Relieva Stratus microflow spacer in an effort to create projected money flow that would bolster Acclarent's initial public offering or acquisition prospects.

In 2010, J&J subsidiary Ethicon bought Acclarent for $785 million. Despite the FDA's rejection of Relieva Stratus as a steroid-delivery product, Facteau and Fabian allegedly marketed the device as such, DOJ claims.

Both were indicted on one count of conspiracy, three counts of securities fraud, four counts of wire fraud and 10 counts of introducing adulterated or misbranded medical devices into interstate commerce.

If convicted, the men face maximum sentence time of more than 100 years each plus a $250,000 fine or twice gross gain.

Senate Device Tax Hearings Set

The U.S. Senate Finance Committee is gearing up for hearings on legislation to repeal the 2.3 percent medical device excise tax, with Sen. Pat Toomey's (R-Pa.) healthcare subcommittee initiating the deliberations.

Two bills to end the tax are being floated in the Senate — the Hatch-sponsored Medical Device Access & Innovation Protection Act and Sen. Ed Markey's (D-Mass.) No Taxation on Device Innovation Act. No date has been sent for the Finance Committee hearing has been set.

In the House, Rep. Erik Paulsen (R-Minn.) has introduced the Protect Medical Innovation Act of 2015—a bill that is similar to one passed last year that did not clear the Senate before the 113th Congress adjourned.

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DALE A. COOKE
Owner, PhillyCooke Consulting

Mr. Cooke's practice specializes in helping FDA-regulated companies develop compliant promotional tactics and improve the promotional review. He is the author of ***Effective Review and Approval of Digital Promotional Tactics*** and is currently at work on a book about compliant social media usage for prescription product manufacturers.

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

MAY 13-14, 2015

EMBASSY SUITES RALEIGH-DURHAM AIRPORT/BRIER CREEK

2 Days, 200 Tips For Improving Your Advertising and Promotion Review Program

FDA marketing scrutiny no longer is limited to magazine and TV ads. Now the agency is poking around, checking signage in tradeshow booths… checking in on Twitter and Facebook….and listening to the physicians and other healthcare professionals you've paid to speak or train.

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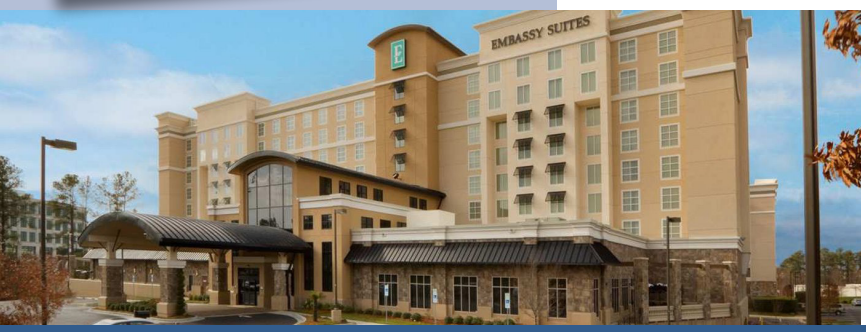

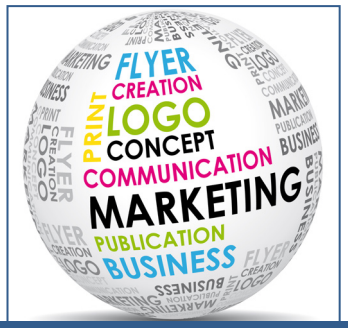

DAY ONE | MAY 13

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 9:45 a.m.

Pre-approval Communications

- How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions

9:45 a.m. - 10:30 a.m.

Disease Awareness Communications

- A review of FDA's help-seeking guidance
- Keys for using disease awareness communications prior to approval. Essential information for continuing communications efforts post-approval compliantly.

10:30 a.m. - 10:45 a.m.

Break

10:45 a.m. - 11:15 a.m.

From Day of Approval through Commercial Launch

- Understanding the timeline and key dates for communications
- Minimizing the pain, while maximizing the impact of initial promotional communications

11:15 a.m. 12:00 p.m.

Essential Advertising & Promotion Regulations

- A review of all of the requirements for product promotion, including product name usage, fair balance, directions for use

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. - 1:45 p.m.

Format-Specific Promotional Requirements

- DTC television promotion
- Brief summary requirements for print promotion

1:45 p.m. - 2:30 p.m.

Substantial Evidence & Other Standards

- A review of the substantial evidence standard, what fails to meet that standard, and when other standards apply

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. – 4:00 p.m.

Off-Label Information

- Avoiding off-label promotion
- Scientific exchange exemption
- Responding to unsolicited requests
- Distributing off-label reprints

4:00 p.m. - 4:30 p.m.

The Promotional Review Process

- An overview of a the standard promotional review process
- Essential traits for any effective process
- Key decisions in establishing or improving performance
- Effective use of metrics for evaluating performance

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO | MAY 14

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. - 9:45 a.m.

Integrating Digital Promotion

- Key considerations for evaluating the compliance of digital promotional tactics and their integration into the overall promotional mix

9:45 a.m. - 10:15 a.m.

Social Media Part 1

- Overview of the platforms, issues, and a review of the status of FDA guidance

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:30 p.m.

Social Media Guidances

- A review of the three social media guidances released in 2014: 2253 Filing, Presenting Risk Information in Space-Limited Contexts, & Correcting Misinformation on Third-party Sites

12:30 p.m. - 1:30 p.m.

Lunch

1:30 p.m. - 3:15 p.m.

Promotional Review Board Practicum

- Workshop participants will apply the lessons from the earlier part of the workshop to specific product promotions. They will work in teams to evaluate specific promotional tactics, determine what (if any) parts of the promotion are problematic, and how to provide direction to a brand marketer to make the promotions compliant.

3:15 p.m. - 3:30 p.m.

Break

3:30 p.m. - 4:15 p.m.

Continuing Regulatory Intelligence: Staying Abreast of Ad/Promo News

- Ad/Promo is an area of ongoing developments. This session will cover the most prominent sources for keeping up with these developments.

4:15 p.m. - 4:30 p.m.

Wrap-up and Adjourn Workshop

"Dale was very engaging and informative. I like the interactive portion where we reviewed actual ads."

— 2014 Workshop Attendee

WHO WILL BENEFIT?

- Advertising and marketing managers
- Social media teams
- Promotion review committee members
- Medical affairs
- Continuing education and tradeshow organizers
- Regulatory compliance officers
- PRC coordinators
- Legal counsel
- Compliance
- Executive management
- Outside ad agencies and marketing consultants

"[Dale is] an animated speaker who seems to know something about everything and has no shortage of opinions. This is potentially very dry and dull material. Dale brings out the exciting and humorous aspects especially well. It's an engaging two days."

— Michael Benedetto, Editorial Group Leader, FCB Health

"This is normally a dry topic, but with Dale it was anything but dry. Dale gave one of the best, most engaging presentations. Dale is highly knowledgeable and also very entertaining."

— Ellen Derrico, Global Head, Market Development - Life Sciences & Healthcare, QlikTech

"As a fellow regulatory professional, Dale is one of the most deeply knowledgeable experts I've heard on this complicated subject. As the pharmaceutical industry is experiencing, digital promotional tactics can trip up even experienced regulatory professionals, but Dale showed how basic principles can be applied to develop compliant promotional materials."

— Kathleen Koons, Sr Regulatory Affairs Manager, DJA Global Pharmaceuticals Inc.

Course Binder Materials:

Full slides from the PowerPoint presentations

Reference documents:

FDA Advertising & Procedural Guidances

- Help-Seeking Guidance
- DTC Broadcast Guidance & Q&A
- FDAAA Pre-Dissemination Review Requirements
- Product Name Guidance (All three versions from 1999, 2012, and 2013)
- Presenting Risk Information Guidance
- Social Media Guidances
  - Postmarketing Submissions Requirements
  - Responding to Unsolicited Requests for Off-label Information
  - Presenting Risk Information in Space-limited Contexts Correcting Third-party Misinformation
- Distributing Off-Label Reprints

Relevant Sections of Code of Federal Regulations

Form 2253

PhRMA Principles on DTC Advertising

PhRMA Principles on Interactions with Healthcare Professionals

Pre-approval Promotion Checklist

Effective Review & Approval Process Checklist

Keys to Evaluating Promotional Review Systems List of Key Resources for Continuing Education

Articles by Dale Cooke

- Developing Compliant Search Engine Marketing Campaigns (Publication Date of September 2014)!
- Industry Standards for Linking Disease Awareness Websites to Product Promotion!
- Patient Testimonial Videos: FDA Actions on Risk Information Presentation!
- Presenting Risk Information on Websites!
- Where Things Stand on FDA Guidance on Social Media (Publication Date of September 2014)

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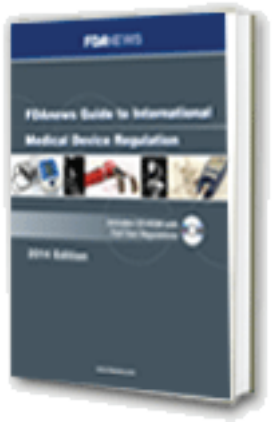

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