INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 2, No. 14
April 4, 2016

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China GCP Update Covers Informed Consent, Record Retention

China is imposing strict requirements for records retention and strengthening responsibilities of sponsors as part of an update to good clinical practices for medical devices.

The China Food and Drug Administration and National Health and Family Planning Commission jointly issued the GCP update late last month. The document — which goes into effect June 1 — marks the first revision to the rules in more than a decade.

The update covers a number of trial-related topics, including preparation, protocol, protection of subjects' rights, management of source documents, as well as the responsibilities of ethics committees, sponsors and investigators.

The new rules stipulate that sites must keep all clinical data and materials for 10 years after study completion. Sponsors must keep study records until devices are no longer in use, Katherine Wang, a partner with Ropes & Gray in Shanghai, says.

(See **China***, Page 2)*

Theranos Questions Findings That Cast a Shadow on its Tests

Theranos is fighting back against study findings critical of the reliability of some of the company's finger prick blood tests.

In a March 24 letter, the company says there are "major problems" in findings published in the *Journal of Clinical Investigation* that questioned the reliability of Theranos' medical tests.

The study, which was funded by Icahn Institute for Genomics and Multiscale Biology and the Harris Center for Precision Wellness at the Icahn School of Medicine at Mount Sinai, examined 60 individuals whose blood was collected either by Theranos' finger prick system or traditional venipuncture, followed by testing by Quest Diagnostics and LabCorp. The assessment took place between July 27 and July 31, 2015.

(See **Theranos***, Page 4)*

China, *from Page 1*

Wang says the document also clarifies that the study sponsor must be a device manufacturer, and international devicemakers must designate a Chinese company as an agent.

Sponsors also will be required to appoint qualified people to perform monitoring activities. If any information affects the study, the sponsor must revise the investigator brochure and obtain approval from the ethics committee.

Wang adds that revised informed consent forms must be approved by the ethics committee prior to communication with study subjects. In addition, the document specifies that a multicenter study is conducted according to a single protocol but at more than three sites. The principal investigator at the lead site will become the coordinating investigator.

Read the revised GCP, known as Order 25, here: www.fdanews.com/03-28-16-CFDA-GCP.pdf (*in Chinese*). An explanation is here: www.fdanews.com/03-28-16-CFDA-GCP2.pdf (*in Chinese*). — Jonathon Shacat

Lawmakers Seek Answers from HHS on Availability of Zika Tests

Two House members are calling on HHS Secretary Sylvia Burwell to provide more details of how the department is responding to the Zika outbreak, saying the current status of diagnostic testing for the virus is alarming.

Reps. Tim Murphy (R-Pa.) and Fred Upton (R-Mich.) wrote the letter last week, following a March 2 hearing of the Energy and Commerce Committee's Oversight and Investigations Subcommittee.

They ask Burwell to explain how the department is working to ensure public-private partnerships and incentives for private companies to produce diagnostics, vaccines and therapeutics against Zika. Currently, no diagnostic tests are commercially available in the U.S. for Zika. Some tests are in use, but they have limitations (*IDDM*, March 4).

The March 29 letter also seeks information on the current status of research undertaken or funded by HHS, and how the department is coordinating with the Defense Department and Agriculture Department regarding research.

In addition, the House members ask how states can use grant money from the CDC for vector control activities.

The letter requests answers by April 12.

Hitting Back at the Virus

Federal authorities have made some strides to combat Zika. The CDC's MAC-ELISA test was authorized for emergency use by the FDA Feb. 26 — the same day Burwell determined that Zika poses a significant potential for a public health emergency.

The FDA subsequently authorized the emergency use of the CDC's Trioplex Real-time RT-PCR Assay March 17. The Trioplex rRT-PCR is authorized to detect and differentiate RNA from Zika virus, dengue virus and chikungunya virus in human sera or cerebrospinal fluid, and to detect Zika virus RNA in urine and amniotic fluid.

On March 30, the FDA authorized an investigational test to screen blood donations for Zika. Availability of the test, developed by Roche Diagnostics, will allow blood establishments in Puerto Rico to resume collecting whole blood and blood component donations.

The cobas Zika test, for use with the cobas 6800/8800 Systems, is for the direct detection of Zika virus RNA in plasma specimens from individual human blood donors.

"The FDA is making this test available while it is still under investigation because there is no equivalent Zika blood donation screening test already authorized for use," FDA spokeswoman Tara Goodin tells *IDDM*.

Read the House letter here: www.fdanews.com/03-30-16-ZikaLetter.pdf. The FDA's authorization letter and notice are here: www.fdanews.com/03-28-16-FDA-Zika.pdf and www.fdanews.com/03-29-16-FDA-ZikaNotice.pdf, respectively. — Jonathon Shacat

Standard on Small-Bore Connectors Focuses on Neuraxial Applications

Aiming to improve the safety of medical device connections in clinical settings, ISO has published a new standard on neuraxial applications for small bore-connectors.

ISO 80369-6: *Connectors for neuraxial applications* specifies the requirements for connectors used in procedures such as anesthesia delivery and monitoring and removing cerebrospinal fluid.

Use of the standard will reduce the risk of the wrong product being administered, says Scott Colburn, convenor of the joint working group developing these standards and director of the CDRH Standards Program.

A small-bore connector is used to link or join medical devices, components and accessories for the purpose of delivering fluids or gases.

Historically, one type of connector was used for many different applications. However, following a series of accidents in the 1990s, the medical community recommended that different connectors be used for different applications to reduce risks. The FDA subsequently endorsed the recommendation.

Last year, the agency added two standards on small connectors for liquids and gases in healthcare applications — AAMI/CN3:2014 (PS) and AAMI/CN20:2014 (PS) — to its list of recognized standards (*IDDM*, Feb. 10, 2015).

Other upcoming ISO standards in the series include: Part 2: *Connectors for breathing systems and driving gases applications*, Part 3: *Connectors for enteral applications* and Part 7: *Connectors for intravascular or hypodermic applications*.

The other ISO standards in the series that are already published include Part 1, *General requirements*, which specifies the requirements for the designs and dimensions of small-bore connectors and Part 20, *Common test methods*, which supports the performance requirements.

Part 6, which costs $161, is available here: www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=50734. — Jonathon Shacat

FDA Revokes MQSA Certificate From Huntington Radiology

In a rare move, the FDA has revoked the mammography quality standards act certificate from a California radiology facility.

The agency revoked the MQSA certificate for California-based Huntington Radiology March 4, marking only the second time the agency has made such a move.

The company has a history of violations dating back to 2010, and has been the subject of several actions taken by the FDA, the American College of Radiology and the State of California Department of Public Health.

The FDA worked with ACR as it performed a review of a sample of mammograms performed by Huntington Radiology that included images taken between September 2008 and September 2010. Results from that review included poor quality mammograms with possibly unreliable results.

The FDA suspended the facility's MQSA certificate in March 2015, and the following month the agency required the facility to notify all patients who received mammograms since Sept. 8, 2014, and their referring healthcare providers, about its problems with mammography quality.

The only other time the FDA revoked the certificate involved Bay Imaging, a group of mammography facilities in Brooklyn, N.Y., says CDRH spokeswoman Angela Stark.

"This is the first time the FDA has published the names of the individuals prohibited from owning or operating a mammography facility for two years," Stark tells *IDDM*.

Huntington Radiology was acquired by Radnet Management in May 2015. Since then, Radnet has been engaged in the process of having the facility recertified by the American College of Radiology, FDA and the State of California, company spokeswoman Laura Foster tells *IDDM*.

Read the notice here: www.fdanews.com/03-30-16-MQSACertificate.pdf. — Jonathon Shacat

Theranos, *from Page 1*

According to the findings, Theranos flagged abnormal test results roughly 1.5 times more often than its competitors, something that could cause patient harm.

The study highlights a difference in total cholesterol results between Theranos and the other two labs, with the startup reporting 9.3 percent lower levels, on average.

"While most of the variability we found was within clinically accepted ranges, there were several cases where inaccurate results would have led to incorrect medical decisions," said Joel Dudley, senior author and Director of Biomedical Informatics at the Icahn School of Medicine at Mount Sinai.

'Flawed and Inaccurate'

Theranos officials were quick to find fault with the study findings, calling them "flawed and inaccurate" in its missive to *JCI*, adding, "We are disappointed that any journal would accept this study for publication."

The company also said that one of the authors failed to disclose that he sat on the scientific advisory board of potential Theranos rival NuMedii — something that could represent a conflict of interest.

Once a darling of the startup world, Theranos has faced intense scrutiny in recent months. For example, it was hit with two 483s, one of which took the company to task for shipping an uncleared device (*IDDM*, Oct. 30, 2015).

In January, the Centers for Medicare & Medicaid Services sent Theranos a letter detailing several deficiencies at its Newark, Calif., laboratory, following a Nov. 20, 2015, onsite survey (*IDDM*, Jan. 29). In early March, the company responded to CMS's findings with a plan of correction and related evidence, detailing how it is addressing the issues.

Read the study here: www.jci.org/articles/view/86318. — Jonathon Shacat

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LDT Developers: Get Cracking On Quality System, Design Controls

Companies that develop laboratory-developed tests should begin to incorporate design controls and establish a quality system ahead of the expected finalization of FDA guidance this year, experts advise.

Establishing design controls now can save companies a lot of trouble down the road as the agency aims to implement its LDT Regulatory Oversight Framework this summer, said Jeffrey Gibbs, director at Hyman, Phelps & McNamara.

LDTs have been held to less strict requirements as in vitro diagnostics, as they were traditionally for in-house use. However, the rise of LDTs being sold over the Internet and to consumers has piqued the interest of the FDA. Now, the FDA is proposing phasing in quality system regulation requirements, the FDA has said.

Thus, Gibbs said, the FDA would find it "comforting" if LDT developers already had quality systems in place.

Karen Becker, managing director at Precision for Medicine, said many newer labs have done so already, as they have partnered with pharmaceutical companies on biomarkers and diagnostics.

Gibbs and Becker made these comments during the Food and Drug Law Institute's Hot Topics in Medical Device Law Workshop March 31 in Washington, D.C. Final guidance on LDTs could come as early as this summer. The draft version was unveiled in 2014.

The FDA's proposal to regulate LDTs has received pushback from stakeholders. For example, more than 50 organizations wrote a November 2014 letter urging the agency to withdraw the draft guidance because it conflicts with existing regulations and would impose substantial new requirements.

Among the criticisms voiced is that LDTs are procedures, not devices. "[They don't] look like any device you've ever seen," Gibbs said. However, he argued that this was a weak argument. "This one is going to be a tough one for the challengers if this ever goes to court," he added.

One potential problem for the FDA, however, is that it has presented its ideas in draft guidance only, rather than pursuing rulemaking, Gibbs said. Still, there are backdoor ways that the FDA can use to regulate LDTs, particularly if they are marketed directly to consumers.

If guidance is finalized, Daniel Kracov, partner at Arnold & Porter, sees the potential for great change in the competitive landscape for LDTs, with many of the smaller labs being wiped out.

As with devicemakers, a presubmission meeting could prove useful for LDT developers, Becker said. "Honestly, our experience with [the Office of In Vitro Diagnostics and Radiological Health] is very positive," he said of such meetings.

Companies concerned about FDA oversight could take advantage of the grandfather clause mentioned in the draft guidance, Gibbs said. That would mean a company would have to get the product on the market in the near-term. "That's something companies are going to have to think about," he added. — Elizabeth Hollis

Ecuador Goes Mobile to Measure Risk for Noncommunicable Diseases

Ecuador has become the first country in the Americas and the second in the world, following Sudan, to use mobile devices to measure risk factors for noncommunicable diseases such as cancer, diabetes, and cardiovascular and lung diseases.

Ecuador is using the devices to carry out the STEPS survey, which was developed by the Pan American Health Organization/World Health Organization.

STEPS was designed to help low and middle income countries build and strengthen their capacity to conduct chronic noncommunicable disease surveillance. It also serves as a harmonizing tool to collect and display data throughout the region. — Jonathon Shacat

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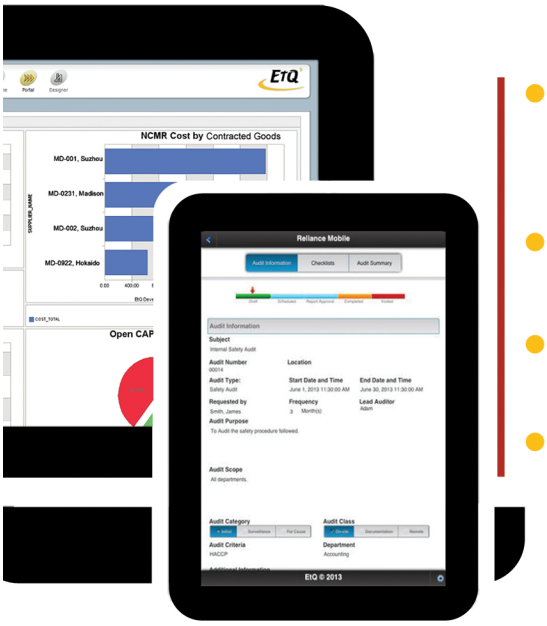

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Radiology Clinic Hit With Multiple MQSA Claims

The third time is not always the charm, as radiology clinic MRI Imaging Specialist learned the hard way following three failed FDA inspections in nearly two years, a recent FDA warning letter shows.

The March 17 letter from CDRH's Division of Mammography Quality Standards — which the agency posted late last month — cited nine violations of the Mammography Quality Standards Act.

Seven of these alleged violations uncovered in the Feb. 17 inspection were classified as Level 2 — or serious — lapses, including inadequate quality control testing and neglected medical audits.

This was the company's third inspection since July 2014, and in all cases the company was deemed to be out of compliance with the MQSA. Prior inspections were conducted July 1, 2014, and June 17, 2015, the warning letter shows.

According to the agency, quality control tests conducted on a review workstation and a mammogram unit were deemed inadequate because they were performed at the wrong frequency.

The letter also cited the company for failing to perform medical audits and outcome analyses annually as well as on each mammogram undertaken and for the facility as a whole.

Additionally, the agency notes that not every positive mammogram was entered into the clinic's tracking system, nor does the facility communicate results adequately due to an apparent lack of a system for providing lay summaries.

Finally, the agency scolded the clinic for apparently failing to respond to its last MQSA inspection report. It also warned that because the apparent repeat violations could signal "serious underlying problems," the agency is prepared to take more drastic action to ensure compliance.

The letter gives the clinic three weeks to respond with a list of all corrective actions taken to address the allegations, along with steps to avoid future violations and sample records to demonstrate an understanding of proper record-keeping procedures.

Read the warning letter here: www.fdanews.com/03-24-16-MRILetter.pdf. — Cameron Ayers

FDA Warns of Dangers Posed by OxySure's Portable Oxygen System

Explosion fears have prompted the FDA to warn facilities and consumers not to use one of OxySure Therapeutic's portable emergency oxygen systems.

The FDA has received multiple complaints related to the use of the OxySure's Model 615, including insufficient oxygen flow, re-breathing of exhaled gases, burns, bruising and exposure to chemicals.

It adds that chemical reactions in the canisters could cause them to explode.

Although OxySure voluntarily recalled replacement cartridges for the model in June 2015, the agency has deemed this action ineffective, according to a safety alert issued last week.

The FDA issued a letter to OxySure in December 2015 requesting the firm identify corrective actions to ensure the product was not being used by customers.

However, the agency says the company has failed to address the safety issues.

OxySure has distributed at least 1,000 units nationwide since June 2013, according to the FDA.

OxySure says it is troubled by the "suddenness and timing" of the FDA's safety notice, and continues to stand by its product.

"The company has meticulously, methodically and systematically worked with the Dallas branch of the FDA on all regulatory issues over time, bending over backwards in the process," a spokesperson for OxySure tells *IDDM*.

Read the notice here: www.fdanews.com/03-30-16-OxySureNotice.pdf. — Jonathon Shacat

BRIEFS

Japan's PMDA Opens Training Center

Japan's Pharmaceuticals and Medical Devices Agency launched the Asian training center for regulatory affairs April 1. Regulators and industry representatives will present objectives and expectations during a commemoration celebration on April 7 at the Imperial Hotel in Tokyo. Establishment of the center was announced in the PMDA's International Strategic Plan 2015 on June 26, 2015, as part of a strategy to build regulatory capacity in partner countries (*IDDM*, Oct. 30, 2015).

Anika Therapeutics Nabs CE Mark Approval

Bedford, Mass.-based Anika Therapeutics has received the CE mark for its combination viscosupplement Cingal for the treatment of osteoarthritis of the knee. In clinical trials, the device — which is administered by injection— demonstrated — superiority over placebo at 12 weeks and patients experienced improvement in stiffness and physical function at 26 weeks, the company says. Previously, Cingal was approved in Canada, and the company is pursuing a sign-off by the FDA.

TGA Schedules Postmarket Workshops

Due to popular demand, Australia's Therapeutic Goods Administration has scheduled two additional workshops on postmarket roles for regulatory affairs representatives in medical device companies. One will be held June 23 in Melbourne and the other July 28 in Brisbane. Scheduled sessions include annual reporting requirements and postmarket reviews. For more information, visit www.tga.gov.au/medical-devices-how-stay-included.

Japan Approves Glaukos' iStent

The Japanese Ministry of Health, Labor and Welfare has approved Glaukos' iStent trabecular micro-bypass stent for use in combination with cataract surgery to reduce intraocular pressure in adults. The stent is approved in adults with moderate open-angle glaucoma who are currently on ocular hypotensive medication. Further, it's the first ab interno micro-invasive glaucoma surgery device approved for use in Japan, according to the company. iStent garnered FDA approval in June 2012. In total, it is approved in 27 countries.

Russia Sees Counterfeit Crackdown in Dentistry

Russia's Federal Service for Surveillance in Healthcare, or Roszdravnadzor, has teamed up with other authorities in that country to find counterfeit medical devices used in dentistry. The effort uncovered counterfeit drugs and devices that were sold in dental clinics across Russia. Roszdravnadzor says it will continue to work on quality control of medical devices used in dentistry.

MedX Wins Incubator License

MedX Ventures Group — an investment and management company with offices in the U.S., EU and Israel — has been selected to receive a license to run an incubator in Or Yehuda, Israel. The incubator is owned by Boston Scientific, Intellectual Ventures, Med-Accelerator and Tel Hashomer's commercialization company and will invest in the medical device, combined medicine and digital health arenas. MedX's portfolio companies are Microbot Medical and XACT Robotics. The incubator program is backed by the Israeli government.

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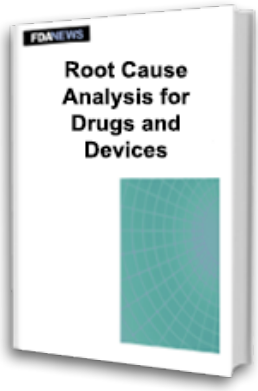

Root Cause Analysis for Drugs and Devices

This management report provides a step-by-step guide to conducting an effective root cause analysis, from recognizing problems that need to be investigated to documenting the investigation so regulators can see you are on top of the situation. Along the way, you'll learn about:

- Gathering the right people to conduct the investigation;
- Developing an accurate problem statement;
- Identifying problems that should trigger CAPAs;
- Various analytical tools that can help narrow the focus of your investigation, including:
  - o Affinity diagrams;
  - o Fishbone diagrams;
  - o GANTT charts;
  - o Trend analysis;
  - o Pareto analysis; and more.
- Documenting the effort in detail; and
- Understanding regulators' requirements and avoiding consequences, such as 483s and Warning Letters.

The report also includes root cause analysis templates readers can customize for their own investigations, including:

- Is/Is Not table;
- Possible Causes and Confirmed Facts lists; and
- Contradiction Matrix.

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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.

"Dale is easy to listen to. The material covered is comprehensive. The sessions covered what I believe is beneficial to those responsible for ad/promo review"

— Tim Williams, VP of Regulatory Affairs, CR Bard

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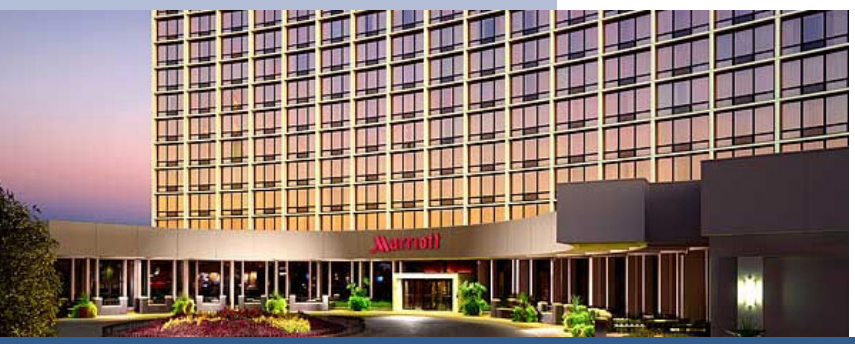

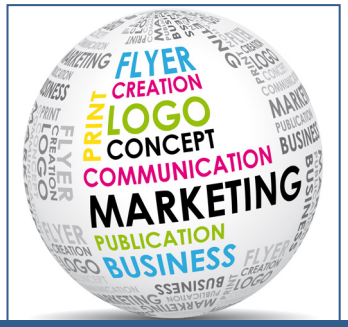

DAY ONE

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

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."

— 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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