INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

South African Regulators Seek Feedback on Device, IVD Guidelines

South Africa's Medicines Control Council has posted four guidelines for public comment covering a range of issues related to medical devices and *in vitro* diagnostics.

The first three documents describe conformity assessment procedures, recalls and withdrawals, and postmarket surveillance and adverse event reporting.

A fourth document includes general information regarding applications for licensing of manufacturers, distributors and wholesalers and registration of devices and IVDs. It revises a document unveiled for implementation and comment in September 2014.

The 96-page guideline covers the basics of the device registration process in South Africa, as well as the classification process and

(See **South Africa***, Page 2)*

IMDRF Aims to Balance Data Collection by 2020

The International Medical Devices Regulators Forum has unveiled its strategic plan through 2020 that places a strong emphasis on striking the right balance between pre- and postmarket data collection.

Over the next four years, the forum will undertake initiatives to support innovation and access to safe and effective devices while working toward regulatory convergence, according to the document.

To that end, the management committee will develop new work items to enhance postmarket surveillance and improve the effectiveness and efficiency of premarket review.

The group names work items it has undertaken to enhance postmarket surveillance, such as the establishment of common principles on registries and the creation of the Medical Device Single Audit Program.

(See **IMDRF***, Page 2)*

South Africa, *from Page 1*

fees. It also describes regulatory requirements related to combination products.

Adverse Events

In the postmarket surveillance guideline, the MCC clarifies that all events meeting three basic reporting criteria should be reported to the health authority, even if they don't involve a patient or user. The criteria are:

- An adverse event has occurred;
- The license holder and manufacturer's product is associated with an adverse event; and
- The event led or may lead to a near adverse event or cause death or injury if it were to recur.

The updated guideline on recalls and withdrawals adds information on quality defect reporting and advises certificate of registration holders to inform the Registrar of Medicines of all quality defects that may result in a recall. It replaces recommendations issued more than 12 years ago.

Recalls must be undertaken in consultation with the MCC. If the product poses an immediate danger over the weekend or on public holidays, the registration certificate holder may, within 24 hours, release information about the recall.

As in the U.S., most recalls in South Africa are conducted on a voluntary basis. However, the MCC may recall a product when the registration has been canceled or if the product is being sold illegally. In such cases, manufacturers, importers and distributors can work with the regulator to decide if a recall is necessary, according to the guideline.

The final document relates information firms must supply for licensing medium- to high-risk (Class C) and high-risk (Class D) devices and IVDs. Firms have six months from the implementation of the guideline and publication of the general regulations addressing medical devices and IVDs to apply for a license to manufacture, import, distribute or export a product.

Comments on all of the guidelines are due Nov. 30. Read the general information guideline at www.fdanews.com/101915-general.pdf, the recalls guideline at www.fdanews.com/10-15-MCC-Recalls.pdf, the conformity assessment guideline at www.fdanews.com/101915-conformity.pdf, and the adverse events and postmarketing guideline at www.fdanews.com/101915-postmarket.pdf. — Elizabeth Hollis

IMDRF, *from Page 1*

IMDRF says it will build on these activities and consider new work items that are in line with these objectives.

In terms of improving the premarket review process, IMDRF is eyeing work items on ensuring the reliability of data submitted to regulatory bodies, improving the quantity and quality of clinical data, developing good review practices to include competence and training for reviewers, creating guidance on risk-benefit determinations and enhancing the suitability of international standards for regulatory authorities and effective regulatory authority involvement at each stage of development.

In addition, the forum will share information on — or challenges to — implementation of outputs in various jurisdictions.

The management committee will develop work plans with timetables for completion, making them available to the public for review.

Finally, IMDRF will continue to enhance transparency and encourage collaboration with stakeholders, including standards development organizations.

The management committee will review progress on the plan and revise it, as appropriate.

The document is available here: www.fdanews.com/101915-IMDRF.pdf. – Elizabeth Hollis

China Provides Details on Device GMP Inspections

The China Food and Drug Administration has issued four guidelines that give additional information for devicemakers awaiting good manufacturing practices inspections.

Covering GMP inspections in general, sterile devices, implantable devices and *in vitro* diagnostics, the guidelines are annexes to the main device GMP regulations issued in January, Ropes & Gray Partner Katherine Wang tells *IDDM*. They offer guidance to inspectors on how to inspect manufacturing facilities, but they also can help companies prepare for inspections because they list what inspectors will look for when they conduct onsite GMP inspections.

"The appendixes set forth principles for the specific types of devices that represent higher risk," Wang says.

Ames Gross, president of Pacific Bridge Medical, tells *IDDM* that the new guidelines should help with the overall quality of medical device manufacturing in China. "There is not much change for foreign companies manufacturing in China, since they already implement their own GMP," he says. "However, the quality standards should improve for domestic Chinese companies that comply with the new guidelines, which would make Chinese-made devices more competitive globally."

It has been a busy year for the CFDA in terms of ramping up device quality. In January, the regulator announced it would beef up its inspections system for medical devices by adding more investigators and improving the performance of quality testing centers (*IDDM*, Feb. 6).

The following month, China released revised GMPs for sterile and implantable devices.

Over the summer, China's State Council unveiled new guidelines intended to make the medical devices approval process more science-based and efficient (*IDDM*, Aug. 21). The guidelines look to raise the review standards to those of international levels while helping enhance transparency. The four annexes are available in Chinese here: www.fdanews.com/101915-china-inspections.pdf. — Tamra Sami

Lawmaker Urges FDA To Take Action on Essure

The drumbeat for the removal of Bayer's controversial implantable contraceptive device Essure is growing louder, with a federal lawmaker becoming the latest to urge the FDA to take it off the market until a well-designed study can demonstrate its safety and effectiveness.

In a letter dated Oct. 9 and addressed to Acting FDA Commissioner Stephen Ostroff, Rep. Rosa DeLauro (D-Conn.), says she is deeply disturbed by health problems experienced by women as a result of Essure, adding that more than 5,000 adverse event reports had been filed.

Essure is marketed by Bayer Healthcare, which acquired the implant with its 2013 buyout of Conceptus.

"A citizen petition filed on behalf of hundreds of women injured by Essure asks the FDA to remove the device from the market," DeLauro writes. "FDA should take immediate action to do so."

Her letter also touches on last month's meeting of the FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, held to discuss the risks and benefits of Essure (*IDDM*, Sept. 25). While no official vote was taken on whether the benefits outweigh the risks, the panel recommended the development of a patient registry to monitor outcomes with the implant.

At the meeting, many women detailed severe adverse events, including bleeding, autoimmune diseases, painful sexual intercourse, unplanned pregnancies, weight gain, tooth and hair loss and excruciating pelvic and abdominal pain. DeLauro took exception with the amount of time — three minutes — each woman was allowed to speak. They also were forced to speak from the audience, rather than

(See **Essure**, *Page 4)*

Essure, *from Page 3*

up front at a lectern, as FDA officials and Bayer representatives had done.

Even expert obstetrician Aileen Gariepy of the Yale School of Medicine was not allowed to speak from the lectern, Delauro writes. Gariepy was among those questioning the data backing Essure and traveled at her own expense to the metting. During her presentation, she said 85 percent of women who got the Essure implant were sterile three months after the procedure. Many women might consider other options with that sterilization rate.

The panel also was not given a chance to hear from women involved in a clinical trial in which the sponsor allegedly changed data on patients' ages and complications, according to DeLauro. She cites three postapproval studies whose data do not include the full breadth of adverse events. Patients allegedly complained that their symptoms, including severe chronic pain, were not accurately documented. At least one woman attested to having her answers to questionnaires changed in her study records.

"Given this background, it appears that Conceptus … systematically grossly underreported symptoms experienced by patients treated with this device," DeLauro alleges.

In addition to questions about the time allotted patients and failure to invite women involved in the clinical trial, DeLauro asks whether the FDA has followed up with Bayer on pain and other severe side effects in postmarket trials, as well as if the agency tried to obtain long-form study records to determine how widespread underreporting, crossed-out answers and other data quality issues were in Essure clinical studies. She also highlights that the FDA has posted only 11 of the more than 3,000 comments submitted to the docket of the citizen petition to remove Essure. She asks when the agency might post more and actually act on the petition.

DeLauro's letter is available here: www.fdanews.com/101915-DeLauro.pdf. — Elizabeth Hollis

FDA Hits New IBM Unit With Warning Letter

Failure to inform the FDA about a medical device correction or removal has earned Merge Healthcare, a developer of medical image handling and processing, interoperability and clinical systems, a warning letter. Word of the letter came just as IBM closed its deal to buy Merge, which will become part of the new Watson Health business, for $1 billion.

According to a warning letter dated Sept. 30, the company issued two notices — one in January and one in April — related to Merge Hemo, which is used as a tool to collect data into the digital patient record. The warning letter states that, in some instances, computers either froze or took multiple short readings of invasive blood pressure as the devices were being used on patients. As a result of having to reboot the systems, patients' vital signs were lost.

The FDA ultimately determined the company's actions with the Merge Hemo constituted a Class 2 recall. The letter chides the company for not alerting the agency about the device correction or removal.

QS Problems

During the June 3 to July 27 visit to the company's Hartland, Wisc., facility, the FDA inspector also found a number of quality systems issues. Specifically, the inspector determined the company had failed to review and evaluate complaints related to the failure of a device and its labeling. It also didn't establish adequate procedures for reviewing these complaints by a formally designated unit.

In a response dated Aug. 12, the company said it was committed to updating its complaint handling procedure. The agency deemed the response inadequate, saying that Merge had failed to update its complaint handling procedure. Further, the company's response didn't include a commitment to performing a retrospective review of quality data sources to ascertain whether other complaints haven't been appropriately documented or provide a timeframe for establishing a unit to handle complaints.

The FDA also takes Merge to task for not adequately establishing procedures for design validation. Devices that have not completed design validation, including software validation, have been shipped for clinical use on patients in a limited availability basis to collect additional feedback prior to the completion of design validation, according to the letter.

For example, one product was shipped for clinical use in cardiac catheterization procedure labs under such a release, the FDA says.

While the company says it is committed to updating the design validation procedure, the FDA has determined that its response is inadequate, as it has not provided an implementation timeframe. Further, it doesn't discuss whether other in-progress projects may be affected by the elimination of the limited availability release.

Documenting

The FDA also chides the company for not documenting design review results, including the date, in the design history file.

According to the letter, records fail to indicate when design reviews were conducted or their results. In its response, the company didn't give an updated procedure for review or a plan for revisiting competed design projects.

The company is committed to implementing corrective actions to ensure compliance with the Federal Food, Drug, and Cosmetic Act and all regulatory requirements, Justin Dearborn, chief executive officer of Merge Healthcare, tells *IDDM*. He adds that company management will work with the agency to ensure the matter is resolved expeditiously.

A copy of the warning letter is available here: http://www.fdanews.com/10-19-15-Merge-WL.pdf. — Elizabeth Hollis

FDA Seeks Stakeholder Input On Animal Device Studies

The FDA has offered its initial thinking on the best practices devicemakers can adopt when conducting animal studies in preparation for a possible IDE submission.

Intended for industry and agency review staff, the draft guidance, titled *General Considerations for Animal Studies for Medical Devices*, is intended to guide sponsors in presenting such data for an eventual marketing application, "while incorporating modern animal care and use strategies," the document states.

Once final, the guidance document will supersede July 2010 guidance covering animal studies for cardiovascular devices.

The document includes a section on study planning and protocol that recommends the study be planned by an individual with appropriate credentials and experience. In addition, the agency recommends an Institutional Animal Care and Use Committee review, assessing all elements of the *a priori* protocol that address animal care and use before study initiation or a major protocol amendment.

The document also includes a section on intraoperative monitoring to involve the observation of heart rate, electrocardiogram, blood pressure and blood gases.

Other areas covered by the document include what information is required for personnel, how to house animals and ensure their comfort, study methods and conduct and the preparation of regulatory submissions.

A *Federal Register* notice announcing the draft guidance's release encourages those sponsors wishing to use an appropriate nonanimal testing to consult with the agency to determine if that method could be assessed for equivalency to an animal test method.

Interested parties may comment on the document through Jan. 12, 2016. The draft guidance is available here: www.fdanews.com/101915-animal-study.pdf. — Elizabeth Hollis

Gasoline Storage Location Draws FDA Warning for Medsource

A container of gasoline stored next to orthopedic trays got devicemaker Medsource into hot water with the FDA and landed the firm a Sept. 24 warning letter for quality system deficiencies.

The company's Tiverton, R.I., facility was inspected March 26 to 31 after which it received a Form 483.

The letter cites the firm for failure to establish proper storage procedures to prevent contamination, failure to establish acceptance activities for the orthopedic trays, failure to establish and maintain CAPA procedures and failure to establish a quality management system.

While the container of gasoline caught the inspector's eye, the firm did not have a procedure for storage of medical devices. Orthopedic trays awaiting delivery to customers were stored in the same area used to inspect orthopedic trays returning to the firm after being used in surgery, the letter says.

The inspector also observed that the firm did not have any acceptance activities for manufacturing the trays, nor did the firm have a corrective and preventive action procedure.

In addition, Medsource had not established a quality management system or a system for notifying managers of quality issues.

The FDA also said that since Medsource modified the surgical trays, they are considered new devices and need to be registered.

The agency also told the company that its Optecure + CCC allograft demineralized bone matrix products are considered medical devices when combined with bone void filler.

The firm did not respond to a request for comment by deadline. Read the warning letter here: www.fdanews.com/101915-Medsource.pdf. — Tamra Sami

Swedish Health Authority Says Beware of Unapproved Apps

Sweden's Medical Products Agency is asking consumers to check whether their mobile medical apps are CE Mark approved.

The reminder comes after reports that certain mobile apps that should be regulated as a medical device are being marketed unlawfully without the required CE Mark.

In a statement, the regulator notes there is a growing number of health and lifestyle apps, many of which offer tips on exercise and training, that are not considered medical devices. However, others are marketed as a way to diagnose or treat a disease or injury, or to examine a physiological process. Examples include those for conception and pregnancy and those for helping with a functional impairment. These should bear the CE Mark.

The MPA is assessing the boundaries between medical and nonmedical apps and will work with international regulatory bodies on the issue. Earlier this year, U.S. regulators cracked down on two companies that claimed their apps could help diagnose skin cancer. The Federal Trade Commission announced settlements with New Consumer Solutions, developer of the Mole Detective, and Health Discovery, which markets MelApp, both of which purport to check moles for melanoma symptoms. (*IDDM*, Feb. 27). — Elizabeth Hollis

Medtech VC Funding In Q3 Tops $820M

Venture capitalists poured about $821.5 million into medtech firms during the third quarter of 2015, representing a sizeable increase over the $634 million raised during the same period in 2014.

As a result, the funding totals for 2015 stand at $2.1 billion, representing an uptick from just under $2 billion at the same point last year, according to data from "PwC/NVCA MoneyTree Report, based on data from Thomson Reuters."

Raking in the most for the quarter with a $26.5 million haul was Munich, Germany-based JenaValve Technology, which develops second-generation transcatheter aortic valve implantation systems. The 9-year-old company, which also has a presence in Irvine, Calif., received the CE mark in 2011 for its JenaValve system.

Coming in second is newly minted San Francisco-based Gritstone Oncology with $25.5 million. Gritstone opened for business this summer and is headed by Andrew Allen, Clovis Oncology's cofounder and former chief medical officer and executive vice president of clinical and preclinical development.

Rounding out the top 3 with $23.9 million is Emeryville, Calif.-based Channel Medsystems, which is focused on women's healthcare. Its cryothermic technology is available for investigational use in Canada, but not in the U.S.

Venture capitalists invested $16.3 billion during the quarter for all industries, bringing the grand total for the year to $47 billion. "Despite a modest downtick in dollars and deals in the third quarter, we are still in the midst of a robust market, and this quarter marks the second highest quarter in aggregate investment dollars since the fourth quarter of 2000," said Tom Ciccolella, U.S. venture capital market leader at PwC.

At the AdvaMed 2015 conference in San Diego, a panel discussed investment trends in medtech startups, concluding that traditional companies with incremental innovation could suffer (*IDDM*, Oct. 12). Brian Williams, director of strategy and innovation, new entrants and healthcare, PwC, told *IDDM* that these companies would have to demonstrate a significantly differentiated therapeutic value to still see funding.

He added that with healthcare increasingly moving to the home, devicemakers will have to appeal directly to consumers. Interest in devices intended for the home is seen in the MoneyTree report with investments in Owlet Baby Care, which developed the Smart Sock baby monitor, and CliniCloud, which makes a medical kit for home use. — Elizabeth Hollis

BRIEFS

St. Jude Scores CE Mark for LVAS

St. Jude Medical has received the CE mark for its HeartMate 3 left ventricular assist system. St. Jude acquired the system after wrapping its purchase of Thoratec earlier this month. The system offers a cardiac support option for advanced heart failure patients awaiting transplantation, aren't candidates for heart transplantation or are recovering from a heart attack. Receipt of the CE mark followed a clinical trial showing the HeartMate 3 LVAS met its primary endpoint of 92 percent survival at six months. HeartMate 3 is being evaluated in an IDE trial in the U.S.

Lumenis, XIO Wrap Up Merger

Israel's Lumenis, which makes energy-based solutions for surgical, ophthalmologic and aesthetic applications, last week completed its merger with an affiliate of the Hong Kong investment firm XIO Group. Lumenis shareholders will receive $14 per share in cash. The two announced in June that XIO would buy Lumenis in a deal worth about $510 million. Lumenis specializes in laser-, intense pulsed light- and radio frequency-based technologies.

Mayo Clinic Wins Grant for Seizure Devices

The National Institutes of Health has awarded the Mayo Clinic a five-year, $6.8 million grant to develop devices to track and treat abnormal brain activity in people with epilepsy. The goal of the research is to develop an implant that can monitor brain activity to predict and prevent seizures. The grant is part of President Barack Obama's BRAIN Initiative focused on disorders such as Alzheimer's and epilepsy.

Recall of Cook Catheters Expanded

Cook Medical has initiated a voluntary recall for select sizes of Beacon tip angiographic catheters, an expansion of the voluntary lot-specific recall issued July 2. The recall covers specific versions of the Torcon NB Advantage Beacon-tip catheters, Royal Flush Plus Beacon tip high-flow catheters, Slip-Cath Beacon tip hydrophilic catheters and Shuttle Select Slip-Cath catheters. There have been 42 medical device reports concerning the Beacon tip angiographic catheters regarding tip splitting or separation, which has the potential to lead to loss of device function.

Groups Focus on Saudi Arabia, Kuwait

From April 23 to 28, the U.S. Department of Commerce and International Trade Administration are expected to lead a Healthcare Technology & Hospital Information Services Trade Mission to Saudi Arabia and Kuwait. The mission, which is supported by the U.S. Chamber of Commerce and the Saudi-American Healthcare Forum, will be geared toward U.S. companies and international hospital groups. Specifically, those that provide hospital operation and management services, information systems and eHealth solutions are encouraged to join. The ultimate goal is to help U.S. firms doing business in those countries to expand their footprint. To read the *Federal Register* announcement, visit www.fdanews.com/101915-Saudi-Kuwait.pdf.

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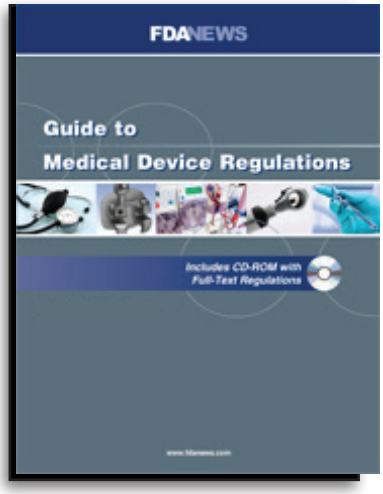

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Mr. Cooke's practice specializes in helping FDA-regulated companies develop compliant promotional tactics and improve the promotional review. He is the author of ***Effective Review and Approval of Digital Promotional Tactics*** and is currently at 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 | NOV. 17

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 | NOV. 18

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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