INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 1, No. 8
Feb. 23, 2015

IN THIS ISSUE

Draft CDER Guidance Sets Rules On Tissue Adverse Event Reporting

Manufacturers investigating adverse events related to human cellular and tissue-based products should review environmental controls and monitoring information for all areas where HCT/Ps were processed to determine the cause and extent of the problem, U.S. regulators say.

This may include temperature and humidity controls, air samples, work surfaces, sinks and drains, personnel and cleaning and disinfection of rooms, according to draft guidance on reporting adverse events involving HCT/Ps. The review should determine what types of microorganisms have been detected and whether any microorganism identified was also detected in a patient infection.

Companies should also determine whether other materials from the same donor were discarded due to contamination, failed environmental testing or failure to meet other preestablished acceptance criteria, the FDA says.

Review Tracking Records

Manufacturers should assess the way in which the HCT/P involved in the adverse event was recovered and processed for potential trouble spots, including deviation from set procedures. And they should scrutinize records related to reviews of the product's incoming bioburden, pre- and postprocessing culture results and whether any microorganisms detected were also found in the recipient. Verifying that the process used to remove microorganisms was validated and properly performed and ascertaining whether other tissues from the same donor were discarded due to contamination should also be part of the complaint investigation, Friday's guidance says.

The FDA also expects manufacturers to look at tracking information. This should include the number of HCT/Ps produced and distributed from the donor involved in the adverse reaction, the number implanted, the number still in inventory and the number that have been sent to other establishments for further processing.

Firms should check their complaint files for reports of problems involving the same donor, infectious agent or reporting

(See **Tissue**, *Page 2)*

Tissue, *from Page 1*

facility, and review those records if necessary, the agency says.

The investigation should include an evaluation of pertinent information about the adverse reaction that could suggest possible causes — for example, symptoms, and outcome of the reaction, the patient's medical history, relevant test results and history of transplants, transfusions, and other procedures that may increase the risk of communicable disease.

Finally, HCT/P makers need to share information on adverse reactions with other establishments using materials from the same donor, so that they can take appropriate steps to prevent similar problems, the FDA says. Companies should design their reporting procedures with patient confidentiality in mind, the agency adds.

The guidance applies to manufacturers of nonreproductive HCT/Ps that are regulated under Section 361 of the Public Health Service Act and 21 CFR Part 1271. These products include pericardium, bone, cartilage, cornea, skin, tendons and vascular grafts.

Manufacturers must report adverse reactions as long as there is a reasonable chance the HCT/P is responsible — even if the relationship between the HCT/P and the incident is unlikely. Companies must report adverse events within 15 days of learning of them.

Comments on the draft guidance are due April 21 to docket no. FDA-2015-D-0349. View it at www.fdanews.com/02-23-15-tissues.pdf.
— Elizabeth Orr

Saudi Guidance Clarifies Rules On Label Format, Language

The Saudi Food and Drug Administration says medical devices meant for use by healthcare professionals should be labeled in English, whether they are in paper or electronic format.

Meanwhile, labels for products that will be used by patients and other nonprofessionals should be in English and Arabic, the FDA says. If it's not feasible to include both languages, Arabic should be used. These labels should be in paper format, recent guidance says.

Labels may contain the product's national listing number, which is issued by the SFDA, but shouldn't include the agency's logo or the establishment's national registry number.

The guidance clarifies requirements in the Medical Devices Interim Regulation, which was published in 2008.

The SFDA will ensure that the manufacturing site of the country of origin, shown on the labeling of imported devices, is covered by documents provided for marketing authorization, the guidance says. Customs officials may enforce different labeling requirements, it adds.

Read the guidance at www.fdanews.com/02-15-Saudi-Labels.pdf. — Jonathon Shacat

FDA Considers Use of Databases To Demonstrate NGS Validity

Manufacturers of next-generation sequencing technology may soon be able to validate the results of new tests by comparing them with data in a curated database, rather than through clinical trials, U.S. FDA officials say.

According to Elizabeth Mansfield, deputy director for personalized medicine in the agency's Center for Devices and Radiological Health, the FDA's current in vitro diagnostic approval pathways follow the concept of "one test, one disease," which is inappropriate given the vast amounts of information genetic sequencing generates.

The National Institutes of Health is funding a clinical genome resource project, compiling data on the relationships between genes and diseases, and the FDA would like to see other similar efforts, Mansfield says. Meanwhile, the agency is working with industry groups to develop database designs — preferring ones with a scalable

(See **NGS**, *Page 3)*

NGS, *from Page 2*

structure and application programming interface for flexibility and ease of use.

An independent body would need to establish standards for database reviews, Mansfield says.

Mansfield says that direct-to-consumer tests, such as those sold by 23andMe, might also fit under this trial-free approach. The information required to establish safety and effectiveness is similar to that needed for tests designed for professional use, and 23andMe's notorious 2013 warning letter related more to the company's failure to follow FDA approval processes than to problems with data.

NGS has been in the spotlight since the FDA issued a December white paper on the topic and President Barack Obama included $10 million in his fiscal year 2016 budget proposal to fund agency efforts on NGS. The FDA was scheduled to hold a public workshop on the subject as *IDDM* went to press Friday.

Eric Lander, a co-chair of the President's Council of Advisors on Science and Technology, backs the use of databases in a Feb. 17 editorial in the *New England Journal of Medicine*, saying it offers the "potential for higher-quality and faster approvals." He cites the FDA's 2013 approval of Illumina's MiSeqDx sequencing platform, based on a database of cystic fibrosis mutations created and curated by researchers, as a step in the right direction.

View the *NEJM* editorial at www.nejm.org/doi/full/10.1056/NEJMp1501964. — Elizabeth Orr

Tubing Set Distributor Warned Over Design Changes, Complaint Handling

Topspins, a specification developer and own-label distributor of IV tubing sets, was warned by the U.S. FDA after making design changes without appropriate validation.

The Ann Arbor, Mich., company made several changes to its Smart Set tubing, including switching from a needle-based to needleless sideport and elimination of a sideport, according to the Nov. 6 letter posted online Tuesday.

But the company had no raw data showing that it performed design verification studies, the letter says. It also lacked documentation supporting the decision to substitute verification for design validation.

Neither of Topspins' design control procedures included important requirements for design validation, such as design risk analysis, that devices conform to user needs and intended uses, and that operating conditions on initial production units, lots or batches are defined.

The investigator also cited the company for not documenting its decision on whether to investigate a complaint on "No Phase Wrap." According to the complaint, flame and smoke were visible from the sleeves on the patient's arms where the wraps were worn.

Failure to Follow Procedures

Meanwhile, on March 26, 2014, the company received Smart Set tubing sets that were out of specification, but no evaluation of the need for an investigation was documented. Topspins also lacked a documented signature of the president authorizing use of the devices "as is."

Topspins' procedure for receiving a shipment requires a certain measurement of the incoming Smart Set tubing set received from a supplier. However, the company had no documented specifications for one version of the Smart Set tubing.

The firm inspected random samples from different boxes of Smart Set tubing for certain versions received on March 26, but its procedures didn't include a statistical rationale for the number of boxes inspected for incoming lots, the letter says.

Topspins' corrective and preventive action procedure was also deficient as it lacked requirements for verification and validation and for implementing

(See **Topspins**, *Page 5)*

Topspins, *from Page 3*

and recording changes in methods and procedures. The warning letter followed an Aug. 5-15, 2014, inspection by the Detroit district office.

The company did not respond to a request for comment by press time. View the warning letter at www.fdanews.com/ext/resources/files/02-15/02-18-15-Topspins.pdf?1424279768. — April Hollis

CMS to Cover Low-Dose CT Screening in Heavy Smokers

The U.S. Centers for Medicare & Medicaid Services has agreed to cover low-dose computed tomography for annual lung cancer screening in certain Medicare beneficiaries.

To qualify for the screening, beneficiaries must be asymptomatic, between the ages of 55 and 77, currently smoking or have quit within the past 15 years, and have a history of smoking one pack per day for 30 years.

Initial screenings require a written order from a physician or qualified practitioner, obtained during a counseling session on lung cancer prevention. Subsequent screenings require a written order obtained during any appropriate medical visit.

GE Healthcare spokesman Benjamin Fox says CMS' decision means that CT systems must be capable of providing images of sufficient diagnostic quality for use in screening and that the dose required to obtain the images is below CMS targets. However, GE isn't aware of any CT scanners that are FDA-cleared for lung cancer screening, he adds. — April Hollis

China Subsidizing Local Exporters, U.S. Trade Rep Tells WTO

The U.S. Trade Representative is accusing China of subsidizing exports of local devicemakers, in direct violation of World Trade Organization rules.

According to a complaint filed by U.S. Trade Rep. Michael Froman, China's Demonstration Bases-Common Service Platform gave export subsidies to manufacturers across seven industries — including medical devices — in more than 150 industrial clusters across the country. The subsidies, totaling nearly $1 billion over three years, included discounted or free services and in some cases cash grants for companies that met specified export quotas.

The claim is backed by a list of 174 official documents that appear to describe the program. Three specifically refer to medical products in the title.

Export subsidies are expressly forbidden under World Trade Organization rules because they create unfair competition.

The U.S. has asked the WTO to step in and settle the disagreement through joint consultations. If the U.S. and China can't reach an agreement, the next step would be to take it before a WTO dispute settlement panel.

Medical products are one of seven industries figuring into Froman's inquiry. The other six are apparel and footware, advanced materials and metals, light industry, specialty chemicals and agriculture. U.S. Rep. Scott Peters (D-Calif.) says the subsidies have been particularly difficult for the medtech industry, which employs about 11,000 people in his San Diego district.

View the WTO filing at www.fdanews.com/02-23-15-subsidy.pdf. — Elizabeth Orr

MHRA Clarifies Electronic Instructions for Use

Medical devicemakers may provide electronic instructions for use as long as the products are intended exclusively for professional users and paper versions are available for instructions that get passed on to patients, according to the UK regulators.

Manufacturers should conduct a risk assessment to show that the safety level obtained by providing the instructions for use in electronic format will maintain or improve upon the paper instructions, the Medicines and Healthcare Products Regulatory Agency says in guidance released Feb. 17.

(See **MHRA**, *Page 6)*

MHRA, *from Page 5*

The electronic version may contain symbols and graphics, but the text must be identical to the paper form. Video and audio files may be offered in addition to the text if it is clear that the information is optional, the guidance says.

The guidance applies to implantable, active implantable and fixed installed devices, as well as standalone software and products fitted with a built-in system that visually displays instructions for use. It does not apply to in vitro diagnostic devices.

The use of electronic instructions for use was authorized in a 2012 European Commission regulation. The MHRA says they could improve safety levels, since the information is less susceptible to loss.

Read the guidance at www.fdanews.com/02-15-MHRA-Guidance.pdf. — Jonathon Shacat

AdvaMed Pushes for Globally Harmonized UDI System

U.S. industry group AdvaMed is working with regulators around the world to ensure a global approach to unique device identification — to avoid scenarios where different countries' UDI systems can't communicate with one another.

So far, the U.S. is the only country that has implemented a UDI system, although its final rule is still being phased in. The U.S. system is largely in line with the International Medical Device Regulators Forum's guidance on UDI.

AdvaMed is encouraged by the fact that some countries are showing interest in following the IMDRF guidance, which allows for local variation as the need arises, but has a consistent foundation, says Jeff Secunda, vice president of technology and regulatory affairs. Canada said recently that it will base its UDI system on the IMDRF model.

The U.S. FDA and European Commission have been working with Chinese regulators and recently received indications that the country may be moving toward use of IMDRF's model as well, says Kimberly Trautman, the FDA's associate director of international affairs.

Erik Vollebregt, an attorney with Axon law firm in the Netherlands, says the EU is looking to implement UDI once the medical device regulations are finalized. It should be compatible with both the U.S. and IMDRF systems, he adds.

In the U.S., UDI is being phased in starting with the highest-risk devices last September. Starting in 2016, Class II devices must bear unique barcodes, and in 2018, Class I and unclassified devices must have UDIs. — Jonathon Shacat

Mobile Apps: Watch Intended Use, Product Codes, Attorneys Say

When it comes to mobile medical apps, the U.S. FDA's classification process may rest heavily on how the manufacturer describes the product, experts say.

"Intended use is pretty important," says Amy Fowler, an associate with Minneapolis, Minn.-based law firm DuVal & Associates. She notes, for example, that a wellness app might fall under

(See **Apps**, *Page 7)*

Apps, *from Page 6*

FDA regulation if the manufacturer's marketing materials say it can be used to treat a specific medical condition.

Intended use can be shown by labeling claims, advertising materials, oral and written statements or implied claims, Fowler says.

For a mobile app to be FDA-regulated, it must claim to cure, prevent, mitigate or diagnose a disease or affect the structure or function of the body, and either serve as an accessory to a medical device or transform a mobile platform — such as a phone or tablet — into a medical device.

Product Codes Important

Currently, about 80 percent of mobile medical apps that go through the 510(k) submission process are cleared within 90 days, says Mark Gardner, also an associate with DuVal, adding that this is longer than the average for other types of 510(k)s. He and Fowler discussed FDA regulation of mobile health apps during a Feb. 18 webinar.

Many apps that might qualify as devices under FDA regulations are subject to enforcement discretion, with the FDA's focus being on high-risk apps that could harm people if they malfunction, the attorneys say. A key consideration for the agency is whether the app can safely be used by a patient without physician oversight.

If an app is regulated as a device, the manufacturer should determine the product code to see what risk classification it falls into. The next step is ensuring that claims made on the product's behalf match the product code.

Of particular importance, Gardner says, is checking whether claims about a Class I app might be off-label.

The attorneys note that individuals who commission software may be subject to manufacturing requirements. Distributors, such as the iTunes store, internet providers, and cloud hosts, however, won't be considered manufacturers, they say. — Elizabeth Orr

AAMI Calls for Unified Approach To Assessing Postmarket Hazards

The Association for the Advancement of Medical Instrumentation is urging the FDA and industry to adopt six principles in evaluating postmarket risks, saying little progress will be made in addressing patient safety until stakeholders agree on priorities.

The white paper, posted online recently, lays out a shared vision of risk aimed at better coordinating and understanding manufacturer and regulator postmarket safety activities, such as recalls.

The first principle, evaluation and judgment, should be conducted by an expert team and include relevant information such as experience with the product or similar devices, historic data and company or community standards, AAMI says. In some cases, the team may need to review a nonconforming product to determine whether it can enter or stay in the supply chain even if no regulatory action is necessary, the group says in a white paper posted online recently. The white paper was developed with industry and FDA input.

Loss-of-Benefit Assessment

Next, an evaluator should conduct a loss-of-benefit assessment for each postmarket issue, considering benefit/risk scenarios for multiple safety actions to find an optimal outcome, the white paper says. Issues to review may include the possibility of introducing a new risk or decreasing the product's benefit, or the potential effects on field shortages, marketshare and other ripple effects.

Regulators and devicemakers should also consider the populations affected by the risk. This means asking whether the device failure or potential shortage pose a greater risk to a specific subpopulation, or whether a device hazard puts others at risk besides the patient, as in the case of a fire risk.

Yet another piece of the puzzle is understanding the use environment as it pertains to risk, the paper says. This involves reviewing transport, hospital and home use and potential interactions

(See **Postmarket***, Page 8)*

Postmarket, *from Page 7*

with other devices. A qualified clinician should take part in this part of the evaluation to help identify potential risks and benefits of specific actions in the clinical environment and suggest ways that changes in medical practices could lower risks in the future, AAMI says.

Once postmarket risks are understood, they must be effectively communicated to stakeholders, the white paper says. Communication strategies should take into account cultural diversities and draw on input from patients, users, healthcare facilities, hospital technicians and community partners.

The final goal is recovering loss of benefit and restoring the device to its full potential, if possible, AAMI says. The risk-assessment and management process should include possible actions if the product's full benefit can't be restored. A risk that was not addressed in premarket analysis should be considered a failure, the group adds.

Comments on the white paper are due May 20 to Lauren Clauser at lclauser@aami.org. View it at www.aami.org/hottopics/risk/AAMI/020615_AAMI_risk_white_paper_draft.pdf.
— Elizabeth Orr

BSX Will Pay J&J $600M To Settle Guidant Row

Boston Scientific and Johnson & Johnson have settled a long-running patent dispute over the botched Guidant acquisition, with BSX agreeing to pay J&J $600 million.

The dispute stems from 2004, when heart device maker Guidant agreed to be purchased by J&J for $25.4 billion. However, Guidant was forced to recall products before the purchase was final, leading J&J to cut its offer to $21.5 billion. The second offer included a clause forbidding Guidant from seeking a higher bidder.

Before the second offer was settled, BSX offered $25 billion to take over Guidant. To ensure that antitrust regulators would approve the deal, the companies agreed to sell Guidant's vascular business to Abbott Labs. After a bidding war, BSX paid $27 million for Guidant.

It turned out, though, that Guidant shared financial records on the product line with Abbott before the offer was announced, which J&J argued was a violation of Guidant's agreement not to seek other buyers. BSX countered that Abbott was entitled to see the financials as a co-bidder. J&J sued BSX for $7 billion in damages in 2006.

After years of delay, the case was heard in New York federal court between November of last year and January. A lower court judge sided with J&J earlier in 2014.

Guidant has already paid $705 million to J&J for breaking the agreement. With the $600 million BSX has agreed to pay, J&J's takeaway from the botched deal totals $1.3 billion.

Tim Pratt, general counsel for Boston Scientific, says the settlement now allows the company to move forward and focus on bringing innovative products to its customers. — Elizabeth Orr

FDANEWS

Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Elizabeth Orr
(703) 538-7652
eorr@fdanews.com

Ad Sales: Jim Desborough
(703) 538-7647
jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

Reporters: April Hollis, Lena Freund, Robert King, Kellen Owings, Bryan Koenig, Jonathon Shacat

President: Cynthia Carter; **Content Director:** Dan Landrigan; **Executive Editor:** Meg Bryant

FDANEWS PRESENTS THE

Multi-attendee discounts are available!

BUILDING A WORLD-CLASS ADVERTISING AND PROMOTION REVIEW PROGRAM

AN INTERACTIVE WORKSHOP PRESENTED BY PHILLYCOOKE CONSULTING AND FDANEWS

YOUR EXPERT SPEAKER:

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

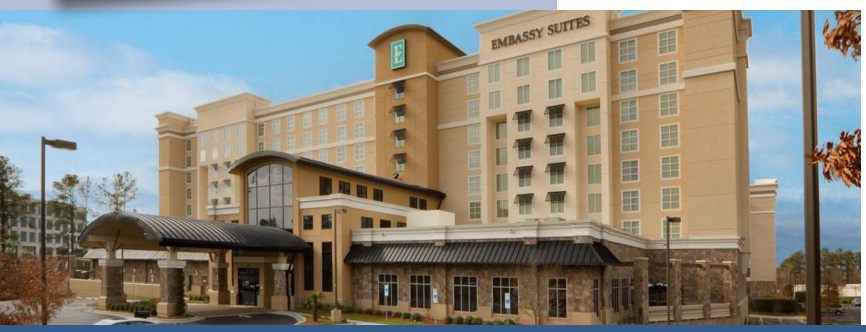
EMBASSY SUITES RALEIGH-DURHAM AIRPORT/BRIER CREEK

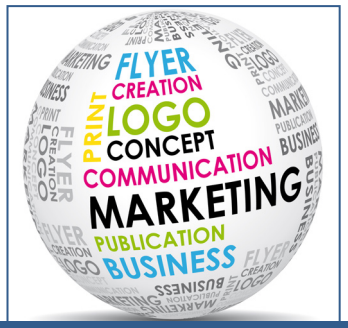
2 Days, 200 Tips For Improving Your Advertising and Promotion Review Program

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.

Come to Raleigh in May for two days of intense learning. You'll arrive back home with a bag full of tricks and tips to keep all your marketing efforts squeaky-clean.

- **Understanding Pre-Approval Communications** Don't get on the FDA's or SEC's radar screens before your product is even approved. Learn how to properly disclose information and remain in compliance.
- **How To Maximize Disease Awareness Communications** Take away valuable tips and tricks for using disease awareness communications pre- and post-approval.
- **Hurray! You're Approved** Building the most aggressive – but compliant – campaign from first day of approval to commercial launch.
- **Assuring Your Promotions Meet FDA Off-Label Standards** Successfully navigating 4 major traps that can earn you a warning letter fast.
- **Itching To Do More With Social Media?** Discover how to get your message out there … without crossing the line.





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)

FDANEWS PRESENTS THE

BUILDING A WORLD-CLASS ADVERTISING AND PROMOTION REVIEW PROGRAM

☐ **Yes!**

Sign me up for the **Building a World-Class Advertising and Promotional Review Program**

	Complete Workshop	Subtotal
Name ..... Title..... Phone ..... E-mail	**$1,797**	
Name ..... Title..... Phone ..... E-mail	Call for Discounts	
Name ..... Title..... Phone ..... E-mail	Call for Discounts	

www.fdanews.com/advertisingpromotion

Toll-free: (888) 838-5578

TOTAL: _____

INFORMATION:

Name _____

Title _____ Company _____

Address _____

City _____ State _____ ZIP_____

Phone _____ Fax _____

Email _____

PAYMENT OPTIONS:

☐ **Check Enclosed:** payable in U.S. funds to FDAnews

☐ **Charge my**: ☐ Visa ☐ MasterCard ☐ AmEx

Card # _____ Exp. Date _____

Signature _____

HOTEL INFORMATION INFORMATION:

May 13-14, 2015

Embassy Suites Raleigh-Durham
Airport/Brier Creek
8001 Arco Corporate Drive
Raleigh, NC 27617

Toll Free: (800) EMBASSY
+1 (919) 572-2200

www.RaleighDurhamAirportBrierCreek.EmbassySuites.com

Room rate: $169.00 plus 12.75% tax
Reservation cut-off date: April 28, 2015

TEAM DISCOUNTS:

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Multi-attendee discounts are available and will be calculated at check out.

2-4 attendees – 10%
5-6 attendees – 15%
7-9 attendees – 20%
10+ attendees – 25%

TUITION:

Tuition includes all conference presentations, conference materials, two breakfasts, two lunches and refreshments.

CANCELLATION AND SUBSTITUTION:

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.