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IN THIS ISSUE

Task Force Lays out Recommendations For Interoperable Postmarket Registries

A task force has unveiled an ambitious set of recommendations for implementing coordinated registry networks as the backbone of a national system for device evaluations.

Specifically, the National Medical Device Registry Task Force, convened under the auspices of the Medical Device Epidemiology Network in June 2014, has proposed the creation of CRNs, which are intended to identify safety signals early to prevent patient harm and aid in device approvals and clearances.

This proposal comes in a new draft document titled *Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research*. The report builds on work started in September 2012 when the FDA released *Strengthening our National System for Medical Device Postmarket Surveillance*, which was updated in April 2013.

(See **CRN**, *Page 2)*

Changes Coming to Device Registrations in Singapore

Singapore's Health Sciences Authority wants stakeholder feedback on updated proposals for submitting similar medical devices in a single product registration application.

Specifically, the authority is seeking input on GN-12-1: *Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria*; and GN-12-2: *Guidance on Grouping of Medical Devices for Product Registration – Device Specific Grouping Criteria*.

The first document is intended to help companies determine whether certain devices may be included together and submitted in one application. It arranges products into the following categories: families, systems, IVD test kits, IVD clusters, groups and single.

(See **Singapore**, *Page 4)*

CRN, *from Page 1*

The system is intended to influence the total product life cycle, in accordance with the Center for Devices and Radiological Health's 2014-2015 priorities to ensure the balance between pre- and postmarket data collection.

"The task force proposes a path forward that combines advances in infrastructure interoperability, quality, and data access with progressive development and implementation of structure core minimum data sets and standardized data dictionaries," according to the report.

To that end, the task force recommends that stakeholders examine existing registries run by state authorities, federal entities, professional societies and other organizations — both national and international. For example, the American College of Cardiology and the American Academy of Orthopaedic Surgeons have developed registries to collect clinical, device and procedure-specific data. The U.S. Veterans Health Administration has a program for its cardiac catheterization laboratories.

Still work remains. "Even as each of these systems may represent the state-of-the-art for its purpose, no one system exists that is sufficient for medical device evaluation," according to the report. "Furthermore, in their siloed and heterogeneous formats, there is currently little ability to synthesize information or continuously accrue safety or benefit/risk knowledge."

Weaknesses highlighted by the report include limited follow-up of patients, lack of a calculable return on investment and variable data quality.

Despite the current weaknesses, linking existing registries, electronic health records and other data together could correct deficiencies in single systems to support reliable device evaluation. Doing so will require the use of a variety of solutions promoting interoperability.

"'Dual purposing' such information systems as components of CRNs reduces the reengineering, beta-testing, staff training and numerous additional cost- and time-sensitive barriers to implementation toward device evaluation applications," the document notes.

The report defines five characteristics that should guide the development of a CRN: the ability to identify medical devices; the use of standardized clinical vocabularies, common data elements and outcome definitions; plans for selecting and creating solution promoting interoperability to link disparate data sources; ideas for crafting inclusive governance; and the promotion of value-based, incentivized sustainability.

The document is available at: www.fdanews.com/083115-surveillance-system-recs.pdf. Interested parties are invited to comment through Oct. 26. — Elizabeth Hollis

German Health Authority Eyes Future of Device, Drug Regulations

With an eye toward providing safe, effective medical devices to patients, Germany's Federal Institute for Drugs and Medical Devices is looking ahead to the challenges and opportunities that could present themselves over the next decade.

The regulatory body, part of Germany's Federal Ministry of Health, has scheduled a meeting for September 15 and 16 in Bonn to discuss the future of health in the country and gain input from the medical device industry, regulators and research institutions. The event will feature a track on challenges facing industry, to include presentations by representatives from the country's Federal Ministry of Health and BVMed, an association that represents Germany's device manufacturers.

A session also is scheduled for the institute's role in assessing complex medical devices.

Other sessions will explore combating counterfeit products, what role the institute can play in the European Medicines Agency's agenda and expectations for the future of industry. — Elizabeth Hollis

The Regulators Are Watching: Avoid Communications Sanctions

FDA officials often attend tradeshows to check out the latest in medical technology. But did you know they're also listening for violative discussions of unapproved and uncleared products?

That warning came from Julie Tibbets, partner at Alston & Bird's food, drug & device/FDA group, during a recent FDAnews webinar on how companies can discuss their product pipelines without falling afoul of federal regulations. She was joined by colleague Matthew Mamak, partner within the firm's financial services and products group, who detailed the U.S. Securities and Exchange Commission's views on the topic.

Under FDA regulations, sponsors and investigators are barred from promoting an investigational device until the agency has approved it for commercial distribution. In addition, they may not represent that the product is safe or effective. The FDA does not, however, put any restrictions on the scientific exchange of information. That's where some confusion has come in.

"Unfortunately, FDA has never expressly defined the full range of what scientific exchange would include," Tibbets explained. However, based on experience, it would appear that dissemination of information in medical publications, as well as medical education and scientific presentations and posters at medical congresses, would pass FDA muster.

"With that being said, FDA's emphasis here is on science and avoiding promotion or marketing of investigational products or uses," she stressed, adding that employees with a scientific background — such as medical officers — should offer this information, rather than sales or marketing personnel.

In terms of products with a pending 510(k) application, the FDA allows companies to display information on that medical device as long as no orders for purchase are taken. Tibbets also recommended that companies ensure that all display or promotional items make clear that the product's application is pending at the agency.

Tibbets noted that the agency enforces compliance in a number of ways, including through reviewing newspapers and social media, listening into conversations at tradeshows and collecting materials and at company booths. Competitors also may serve as sources of intelligence.

In addition, the FDA utilizes the "Bad Ad" program, through which healthcare providers may report violations related to printed literature and communications that may have occurred.

Devicemakers making inappropriate communications risk receiving an untitled or warning letter. For example, Advanced Magnetic Research Institute International was hit with a warning letter in 2014 for marketing a device as safe and effective before it was approved or cleared. Violative statements included: "The rate of healing can be accelerated to be much faster than the typical healing rate of the human body," and "The safety of the induction of high strength magnetic fields was well established during toxicity studies performed for the FDA approval of the MRI." However, it wasn't a competitor or healthcare professional who reported the activity, but rather FDA inspectors who were looking to see whether the clinical trials activities and procedures related to the device complied with applicable federal laws.

Some general rules of thumb companies should keep in mind include the following:

- Always include the word "investigational" when describing an unapproved or uncleared product;
- Don't make unsupported statements regarding safety and effectiveness; and
- Don't use promotional terminology.

SEC Requirements

As Mamak noted, the main job of the SEC is to protect investors. To that end, it requires

(See **Webinar***, Page 4)*

Singapore, *from Page 1*

To be considered part of the same device "family," for example, products should meet the following criteria:

- They are from the same product owner;
- They are in the same risk classification;
- They have the same common intended purpose;
- They have the same design and manufacturing process; and
- Their variations are within a permissible scope, e.g., have a similar physical design, or have the same risk profile.

To help industry, the document provides a table listing permissible variants, as well as a flowchart to aid in determining whether a grouping of medical devices as a family is appropriate. It provides similar details for the other categories as well.

Stakeholders wanting the HSA to reconsider or review any aspect of this document may notify the authority by e-mailing hsa_md_info@hsa.gov.sg with the subject line "Request for review of GN-12 grouping criteria." The HSA will review all requests and update the documents as needed. Updates will occur once every six months.

The second document gives an overview of whether certain models of specific devices may be submitted in one product registration. It touches the following products: Class A and B dental medical devices, hearing aids, immunohistochemistry in vitro diagnostic reagents, fluorescence in situ hybridization probes in vitro diagnostic reagents and in vitro fertilization media.

The documents will go into effect Oct. 1.

The authority implemented the grouping system in 2008 to aid in registration of multiple models of similar medical devices that have the same intended purpose. "This eliminates unnecessary resource burden for both the industry in preparing and for the regulator in reviewing multiple submissions for similar devices with common technical validation," an HSA spokesperson tells *IDDM*. "As a result, this enables timelier access of medical devices for patients' clinical need."

The move is part of an ongoing initiative by the HSA to streamline its processes for the filing of product registration. The authority holds sessions with stakeholders to gauge their opinion and solicit feedback. The next session is scheduled for September and attendees will offer their views on the revised documents how previous feedback affected the latest versions.

GN-12-1 is available at www.fdanews.com/083115-group-general.pdf, and GN-12-2 is available at www.fdanews.com/083115-group-specific.pdf. – Elizabeth Hollis

Webinar, *from Page 3*

companies to disclose information that is material and could influence investors.

"Something material is information that would be important to a reasonable person in deciding whether or not to buy shares in the company," he said. "I think that's simpler to understand and difficult to apply."

Mamak agreed that sometimes it is difficult to determine what to do when information is material.

Many times, the answer is to immediately issue a press release and file an 8-K with the commission. However, if a company wants to wait to disclose the information, he said companies can offer stock answers to investors and analysts ahead of time to stay in compliance.

If a company does decide to make information public during a future conference, rather than in a press release, Mamak advised companies to limit the number of people who know what's in the disclosure ahead of time and to prepare a script so the presenter knows what to say at the event.

If someone within the company makes an inadvertent disclosure, that information must be made public within 24 hours or the next trading day. — Elizabeth Hollis

MDUFA Comments Call for Improved Review Times, Better Staff Training

As the FDA continues negotiations with industry on reauthorization of the Medical Device User Fee Amendments for 2018 to 2022, stakeholders have offered recommendations for improving the program.

Returning review times to pre-user fee program levels and ensuring predictable application evaluations are two themes that appear in comments to a docket posted ahead of a July 13 public meeting that started the clock on the MDUFA reauthorization. Comments were due Aug. 12.

LifeScience Alley, which represents life sciences businesses in Minnesota, says improving review timetables is crucial to encouraging innovation.

"We urge the FDA to make review timetables, consistency and predictability a highest priority and to implement the changes necessary for rapid improvement," according to the group's comments.

The Medical Imaging & Technology Alliance voices similar concerns, noting that "increased and unpredictable data requests" have led to inconsistent use of the interactive review process. Decisions on 510(k)s are taking longer than the historical average, with reviewers increasingly asking applicants to submit additional data.

Training Concerns

Comments also urge the agency to hire and train staff to ensure consistency in application reviews.

As the American College of Cardiology notes, understanding the complexity of medical devices requires training and a scientific background. However, those with the knowledge and skillsets to fulfill these duties often are wooed to the private sector with the promise of higher salaries.

While that may continue to remain a problem, the ACC encourages the FDA to engage with national medical specialty societies to develop programs to enhance the educational development of staff. It also reminds the agency of its Network of Experts, which is designed to identify clinical experts to help CDRH employees. This program, according to the ACC, has not been utilized adequately.

"The college encourages the agency to better promote this program to its staff and to provide it the necessary resources," the comments note. Beyond that network, the agency should allocate funds to support infrastructure to provide the agency with access to experts in the appropriate fields.

The American Association of Orthopaedic Surgeons recommends that FDA personnel participate in research and scientific meetings to gain knowledge and develop solid working relationships with industry. MITA agrees, adding that there should be qualitative goals for training, industry-FDA meetings, regulatory science and guidance development.

Postmarket Surveillance

Comments also praise the agency for enhancing postmarket surveillance and adopting a total product lifecycle approach to ensure the safety of devices.

"It is impossible to know everything about a medical device from a randomized clinical trial; a device's full capabilities and problems will not be identified until it is used and observed in the real world," the ACC says.

To further improve postmarket surveillance, the group recommends that MDUFA IV include funding for the following activities:

- The implementation of a National Medical Device Postmarket Surveillance System Planning Board, as issued by the Brookings Institution earlier this year (*IDDM*, Feb. 27);

(See **MDUFA Comments**, *Page 6)*

MDUFA Comments, *from Page 5*

- The development and ongoing maintenance of medical device registries to collect real-world data;
- The identification of novel techniques for postmarket surveillance, such as the DELTA pilot studies in the National Cardiovascular Data Registry; and
- The drafting and implementation of regulations and guidance to address issues related to the use of existing data sets for FDA-regulated activities.

Meanwhile, the Pew Charitable Trusts says postmarket surveillance could be enhanced through the creation of a body dedicated to device data collection. That entity would encourage the adoption of common data standards; ease the sharing of data on medical devices from electronic health records, claims and registries across the healthcare system; and support standards for the capture and exchange of unique device identifiers.

The organization also promotes utilizing user fees to include UDI in the postmarket surveillance Sentinel program, which currently uses claims data to examine the safety of drugs. Congress required the FDA to expand the program to devices in 2012, and Pew says the agency worked on ways to expand Sentinel to evaluate to healthcare technology.

The comments are available at: AAOS: www.fdanews.com/083115-AAOS-comments.pdf; ACC: www.fdanews.com/083115-ACC-comments.pdf; LifeScience Alley: www.fdanews.com/083115-lifescience-alley-comments.pdf; MITA: www.fdanews.com/083115-MITA-comments.pdf; and Pew: www.fdanews.com/083115-Pew-comments.pdf. — Elizabeth Hollis

Doctor Faces Time for Implanting Unapproved IUDs

A California doctor could serve up to 20 years in prison for treating patients with an unapproved intrauterine device that he purchased over the Internet.

In a case filed in the U.S. District Court for the Eastern District of California, the federal government accused Paul S. Singh, 55, of buying unapproved IUDs sold by online pharmacies and implanting them in women from April 2008 through June 2012. Patients were unaware they were being treated by an unapproved device, and several later experienced complications.

These devices were not identical to the ParaGard T-380A, the only approved IUD that uses copper as an active ingredient. Using unapproved copper-containing IUDs puts patients at increased risk for pelvic inflammatory disease, ectopic pregnancy and hysterectomy.

FDA representatives confronted Singh over his scheme in August 2010, and he agreed to stop using the unapproved devices. Despite this promise, he continued to implant women with the products purchased over the Internet, billing them and their insurers for the approved IUDs.

When patients complained of complications, Singh reinserted the IUD instead of removing it. Some patients ultimately went to other doctors to have the devices removed.

"Medical doctors have a special responsibility to make the best choices for their patients. When they ignore that responsibility and use unapproved medical devices, they put patients' safety and health at risk," says Special Agent in Charge Lisa Malinowski, FDA Office of Criminal Investigations' Los Angeles Field Office, in a statement. "Our office will continue its work to ensure that doctors and other healthcare professionals understand the consequences of using medical products that have not been approved by the FDA."

Singh is scheduled to be sentenced Nov. 23. In addition to prison time, he could face a $250,000 fine. — Elizabeth Hollis

Report: Medtech Mergers Could Break $100B Barrier this Year

During the first half of 2015, the total value of closed medtech mergers came in at $83 billion — a figure that tops some full-year figures from the past decade.

If this trend continues, the value of all mergers and acquisition deals in medtech could surpass $100 billion for the first year ever, according to a report from EP Vantage.

The report notes that there is no firm pattern in terms of M&A targets, with a range of technological areas involved. While the two biggest deals — Medtronic-Covidien and Zimmer-Biomet — involved scale and consolidation, many others saw companies entering new areas altogether. For example, Eurofins Scientific, which is active in food and pharmaceutical products testing, entered the *in vitro* testing arena when it bought Boston Heart Diagnostics.

For example, divestitures also propped up the numbers. Siemens took the fourth and fifth spots in terms of priciest deals with the sale of its hospital information technology business to Cerner for $2.7 billion and the shedding of its hearing aids product line to EQT Partners for $1.3 billion.

A Kinder FDA?

The report also notes that "a ray of sunshine" beamed from the FDA in terms of PMAs of HDEs — representing good news for innovation. The total number for both types of application approvals was 26 devices. If this trend continues, 2015 could be the best year for innovative medical devices coming to market since 2005. By way of comparison, there were 33 such approvals for all of 2014 — a 43 percent increase over 2013.

Approval times also are holding relatively steady. During the first half of 2015, the average approval time was 17.1 months, slightly off the 16.7 months for all of 2014. However, those numbers are better than the average 26.9 months for 2013.

The cardiology field saw 11 approvals — the same number for all of last year.

According to report, the faster FDA hasn't been met with universal applause, citing a July 17 op-ed in *The New York Times* scolding the agency for allowing unsafe technologies on the market by adopting a more relaxed attitude toward clinical data.

"In some ways, it seems that the agency cannot win: the U.S. is widely believed to be more stringent than Europe in its assessment of medical devices, and efforts to tighten up European regulation have met with fierce resistance by industry lobbyists and patient groups," the report's authors write. They add that the two systems might meet in the middle, and companies could stop seeking CE mark certification before trying to enter the U.S. market.

Not all is rosy for the sector, however, as only $1.6 billion was raised in venture funding. The authors note that the first half of 2014 saw three rounds that exceeded $100 million. This year, no company has broken $60 million.

The half-year figures for initial public offerings remained fairly steady over the last half of 2014, with companies raising $705 million versus $723 million.

"With the huge and exciting changes that have gripped the industry over the past year having for the most part been brought to their respective conclusions, the sector seems to have attained a level of stability," Elizabeth Cairns, EP Vantage medtech reporter and co-author of the report, says in a statement. "But start-ups are facing a worsening funding gap, and it will be crucial that this eases if a steady flow of safe and effective medical technologies is to be maintained."

The report is available for download at www.evaluategroup.com/public/Reports/EPVantage-Medtech-HalfYear-Review-2015.aspx.
— Elizabeth Hollis

BRIEFS

Faulty Connector Prompts Teleflex Recall

Teleflex Medical has recalled 62,882 units of its Hudson RCI Sher-I-Bronch endobronchial tube because the double swivel connector may break or separate on the tube while it is inserted into a patient's airways. The recall — involving 12 product codes — covers devices manufactured from October 2013 to April 2015 and distributed through May of this year. Earlier this summer, the recall of Hudson RCI Lifesaver single-patient use resuscitator was announced after reports of oxygen intake ports becoming blocked, preventing the delivery of breathing support.

EU OKs St. Jude Pain System Labeling

St. Jude Medical has received CE Mark approval for MRI conditional labeling of its Prodigy MRI chronic pain system with select leads. The launch will ensure patient access to the company's proprietary burst stimulation and traditional tonic stimulation. The Prodigy MRI system will become the market's smallest MR-conditional rechargeable implantable pulse generator, according to the company. Octrode percutaneous and Penta 5-column paddle leads have received MR-conditional labeling and are approved for use with Prodigy MRI.

Medtronic to Buy Twelve for $458M

Medtronic has reached an agreement to buy a company focused on transcatheter mitral valve replacement. The device giant will buy Redwood City, Calif.-based Twelve for $458 million — $408 million upfront, and the remaining $50 million after a TMVR device in development gains CE mark approval. Twelve is the 12th company spun out from the medical device incubator The Foundry. "We have followed the transcatheter mitral valve space closely and firmly believe that Twelve has the most novel technology along with a strong, proven team," says Sean Salmon, senior vice president and president, Coronary & Structural Heart, Medtronic, in a prepared statement.

Greatbatch to Buy Lake Region Medical

Frisco, Texas-based Greatbatch has offered to buy Lake Region Medical, formerly Accellent, for about $1.7 billion in cash and stock. The proposed combination would result in one of the largest medical device original equipment manufacturer suppliers in the world, serving the cardiac, neuromodulation, vascular, orthopedics and advanced surgical markets, according to a Greatbatch statement. Wilmington, Mass.-based Lake Region's portfolio includes electrophysiology, oncology, laparoscopy and arthroscopic products.

BD Unit Buys Cellular Research

Becton, Dickinson's life sciences unit has scooped up Menlo Park, Calif.-based Cellular Research for an undisclosed amount. The two companies already have partnered to develop single cell analysis workflows for Cellular Research's Precise product line and BD's FACS instruments and software. "The addition of Cellular Research builds on our GenCell acquisition and underscores BD's commitment to a genomics strategy focused on next generation sequencing (NGS) sample preparation," says Linda Tharby, executive vice president and president of BD Life Sciences, in a prepared statement.

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DALE A. COOKE
Owner, PhillyCooke Consulting

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

"Dale is easy to listen to. The material covered is comprehensive. The sessions [redacted] those responsible for ad/promo review"

— Tim Williams, VP of Regulatory Affairs, CR Bard

NOV. 17-18, 2015

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- **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 | 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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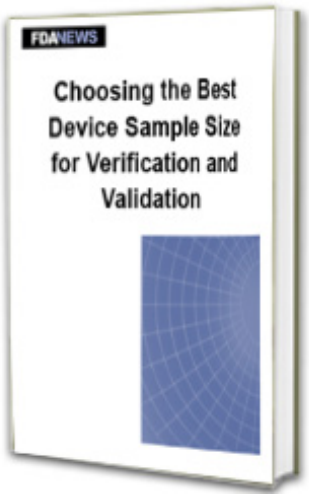

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