CENTER FOR COMMUNICATION COMPLIANCE

www.CommunicationCompliance.com

- Compliance is priority #1 for drug, device, and biotech companies
- Government officials have expressed ongoing concern about how industry is promoting its products in today's dynamic, high-stakes environment
- Industry insists that employees and agencies be knowledgeable about the regulations
- Effective promotion is critical to a product's success

TRAIN AND CERTIFY IN PROMOTIONAL REGULATORY COMPLIANCE TO BECOME A MORE COMPLIANT AGENCY PARTNER…

…Deliver more creative ideas that fall within regulatory guidelines

- ✓ Reduce heavy redlining of promotional documents by regulatory
- ✓ Be more effective in copy review meetings

…Get promotional materials out the door quicker through faster copy review

- ✓ Materials meet basic regulatory requirements, so everyone saves time
- ✓ Great ideas see the light of day

…Protect profit and grow new business

- ✓ Increase profitability by reducing unnecessary redoes
- ✓ Grow new business by positioning compliance as a competitive edge

…Create a corporate culture of compliance

- ✓ Communicate that compliance is a priority; assign qualified staff to clients
- ✓ Facilitate the transfer of regulatory knowledge more quickly

It's easy…with job-relevant, expert-developed, and current tools accessible online, 24/7, you get everyone on the same baseline and ensure agency teams are qualified.

The CCC Regulatory Compliance Test (RCT) certifies competency in each channel. CCC training directly correlates with the RCT.

Commonly Asked Questions

- **How do I know CCC training and certification are valid?** Every product is reviewed by experts**:** CCC's Advisory Board is composed of former FDA officials, and legal & regulatory thought leaders.
- **Will training make my agencies less creative?** It's actually *easier* to be creative when you know the regs. Plus, CCC offers a course in how to remain creative in a regulated environment.
- **What does the advertising training/certification address?** See attached list of job-relevant subjects.
- **Can I confirm my staffers are trained/certified?** They get a dated certificate. You get confidential reports broken down by staffer name.
- **How quickly can you implement?** Start up is immediate. Passcodes can be provided in 48 hours.
- **Can I certify just select staffers?** Certification is a per-person cost and can be purchased for any number or combination of staffers.

Materials and Programs Addressed

Advertising

- ✓ Sales aids
- ✓ DTC advertising
- ✓ Coming soon ads
- ✓ Reminder ads
- ✓ Institutional and disease awareness ads
- ✓ Comparative claims and claims of superiority
- ✓ Web sites
- ✓ Exhibits

Promotional Medical Education

- ✓ Speaker's Bureaus
- ✓ Presentations at scientific meetings
- ✓ Contractual arrangements with speakers, consultants, ad board members
- ✓ Publication plans
- ✓ Speakers' fees
- ✓ Slide kits
- ✓ Gifts to physicians
- ✓ Social events and sponsorships
- ✓ Mechanism of action (MOA) and other videos

Public Relations (investigational and marketed products)

- ✓ Press releases
- ✓ VNRs
- ✓ Media tours
- ✓ Web sites and webcasts
- ✓ Spokespeople
- ✓ Media training

Patient Relationship Marketing

- ✓ Interactive Design
- ✓ Content Development & Copy Strategy
- ✓ Brand Integration
- ✓ Relationships with Third-party Groups
- ✓ Patient Consent & Privacy

Questions Addressed

Advertising

- ✓ Can we use a competitor's published data in promoting our product?
- ✓ Our company has just completed an open-label study whose findings demonstrate that the product has a better efficacy profile than was shown in the Phase III trials. Can we use these open-label data in our advertising?
- ✓ How many of the most common adverse events for a product need to be listed to ensure that it is fairly balanced? Is there a specific number that the FDA typically looks for?
- ✓ Do we have more latitude with promotional materials that are not intended to be left behind versus promotional materials that are? Do such materials need to be annotated in any special way, such as "Not for external distribution"?
- ✓ In our advertising, we want to highlight several specific data points from our Phase III clinical study. Would this be considered "cherry picking"? What are the guidelines?
- ✓ What are the guidelines with respect to positioning fair balance relative to claims? A lot of these guidelines reflect what seem to be "arbitrary" rules that vary from one promotional review committee to the next.
- ✓ We are preparing a DTC TV ad, but we just received a warning letter from the FDA saying that our Web site is out of compliance, so we have temporarily shut it down. Since we don't currently have an active Web site to which consumers can be referred, can we still go ahead and put the ad on the air? Are there any special steps we need to take?
- ✓ We are considering using a celebrity in our DTC TV ad. However, this celebrity doesn't actually have the disease. Does the celebrity have to have the disease? Also, does he or she have to be using the product we are advertising?
- ✓ We want to send a letter to physicians claiming that our product is the most prescribed in its class. What kind of data is needed to support that type of statement?
- ✓ What are the rules regarding Internet promotion? Is Internet promotion considered labeling or advertising for purposes of the regulations – and what difference does it make?

Promotional Medical Education

- ✓ Phase III trial data has just become available for a new product under development. What kind of meetings can be held with the experts in the field at this point of drug development?
- ✓ We are retaining nationally known physicians for our Advisory Board. What is considered a fair market fee? Several physicians have physician spouses – can we pay their expenses as well? If they meet once or twice a year at resort locations to discuss the latest product data, research and company plans, is that okay?
- ✓ Just before a scheduled presentation, an expert speaker reads a just-published paper in a major journal about your drug. The data is not consistent with current labeling. Should the speaker be allowed to share the data, given his/her expertise and the fact that the data *was* published in a top peer-reviewed journal?
- ✓ A company developing a new product wants to hold a social reception during a national medical society meeting. The plan is to invite attending specialists who are potential prescribers. What are the parameters for holding this type of event? Can we be selective in who is invited? Are there limitations on answering questions about a product under development?
- ✓ Our company wants to create "back-up" or "supplemental slides" for use by speakers in response to potential questions about investigational uses for the approved product. How many back-up slides would be appropriate, and what should they include or not include?
- ✓ What guidelines need to be followed in identifying authors for publication plans? Can "ghost writers" or free-lance contract medical writers be part of the writing team? If so, should they be listed/not listed as among the authors?

Public Relations

- ✓ What do I need to know about selecting and training patient spokespeople – do they need to represent "the typical patient"? What precisely does the phrase "typical patient" mean?
- ✓ Can patients be interviewed without their physician? What kind of questions can patients answer about the product?
- ✓ What about the choice of physician spokespeople? How many physician spokespeople can the company hire?
- ✓ If the physicians selected for the media tour have experience with the product for another use that isn't approved, what can they say or not say about that use -- even if they themselves prescribe the product outside of labeling??
- ✓ What if the physicians think that the product is superior to competing treatments – are there any "watch-outs"?
- ✓ Are there special considerations when using celebrities as spokespeople for promoted products?
- ✓ We have a key opinion leader quote that we want to use in our press release and DDMAC says it is misleading and to revise it … but the KOL will not agree to change their quote. What should we do?
- ✓ A product is already approved for one indication, but this study investigated it for another use? Can manufacturing shots of the product be used in VNRs or B-roll?
- ✓ Is a company allowed to issue a press release after an advisory committee meeting, and if so does it have to be submitted to the FDA? Can a company spokesperson speak to the media during a committee meeting?
- ✓ I heard the First amendment protects press releases; is this true?
- ✓ I heard that the FDA and SEC are collaborating? Does it make a difference that our press releases are intended to convey information only to investors and not to doctors?
- ✓ My client has a drug approved as an accelerated product. What do I need to know about the promotional aspects?
- ✓ What about products with black box warnings – can we promote them in the same way as a campaign for marketed products with no warning?

Patient Relationship Marketing

- Interactive Design
  - ✓ What are the rules regarding Internet promotion in the new era of interactive media?
  - ✓ What kind of external Web sites can we link users to in order to provide additional reference materials? Are there potential risks with such links?
  - ✓ What are the guidelines about providing patients with access to risk information, and how might they change?
  - ✓ What are the regulatory considerations surrounding Search Engine Optimization (SEO) techniques and tactics?
  - ✓ What are recent FDA enforcement actions in regard to Internet promotion and what lessons can be drawn from them?
  - ✓ What are the specific policies and guidelines for Web sites? For blogs, social networking sites, media, patient forums, chat rooms, and other new media? In particular, how much monitoring do we have to implement? Do we have to report adverse events that are uncovered? How do we respond to discussion of out-of-label use?
  - ✓ What are the regulatory issues affecting branded vs. unbranded and sponsored vs. unsponsored Internet sites?

- Content Development & Copy Strategy
  - ✓ What are the FDA's guidelines regarding promotion and labeling?
  - ✓ What are the guidelines with respect to positioning fair balance relative to claims? What does FDA consider adequate basis for promotional claims?
  - ✓ What are guidelines for developing patient-directed copy for Disease Awareness sites?
  - ✓ What do I need to know about selecting patient testimonials – do they need to represent "the typical patient"? What precisely does this phrase mean?
  - ✓ What are the policies and guidelines regarding the use of spokespersons? If I use a celebrity, does he/she have to have the disease/used the product?
  - ✓ When can we use market research data in a promotional campaign?

- Brand Integration
  - ✓ Exactly how should the generic name be positioned vis à vis the brand name?
  - ✓ What format and layout factors do we need to consider when developing promotional materials in order to maintain fair balance? Can factors like type size and spacing actually lead to violations of FDA guidelines?
  - ✓ Are there any special regulatory considerations when promoting a drug that has a Boxed Warning? Do we have to use the Warning's exact wording?
  - ✓ Are we ever allowed to make comparative claims about the product we are promoting? Can we say it is "superior" and if so what data do we need?

- Relationships with Third-party Groups
  - ✓ Does the FDA prohibit companies from dealing with patient groups? What about Congress?
  - ✓ Does the FDA or Congress prohibit companies from dealing with professional associations?
  - ✓ What do we need to know about these relationships with regard to regulatory compliance?

- Patient Consent & Privacy
  - ✓ What is HIPAA? What is its purpose in regard to preserving patient privacy, and what specific types of patient information does it protect?
  - ✓ What are the implications of HIPAA for pharmaceutical companies and their agencies in regard to privacy and patient consent? In what ways do they have to be transparent in regard to the use of patient information and what privacy policies should they have in place?

Check out the Internet Marketing and Social Media Curriculum on our Web site