

## Course Curriculum Presented by the Center for Communication Compliance (CCC)

### Regulatory Compliance 101

#### AN OVERVIEW OF PATIENT RELATIONSHIP MARKETING

#### Course Focus

What healthcare communication professionals (inside companies, at agencies, consultants) need to know about regulatory compliance for patient relationship marketing (PRM) programs.

#### Audience

Any professional in the pharmaceutical, biotech, or device industry who works with, designs, executes, reviews, or oversees programs in patient relationship marketing, including direct-to-patient (DTP) programs.

#### Course Format and Access

- 3 one-hour modules: lecture and Q&A
- 24/7 on-demand access from CCC Web site; may be viewed as often as desired

#### Course Content

- Understand the rules and guidelines imposed by regulatory agencies, industry associations, and trade groups:
  - ✓ Food and Drug Administration (FDA)
  - ✓ Office of the Inspector General (OIG) of the Dept. of HHS
  - ✓ Department of Justice (DOJ)
  - ✓ Pharmaceutical Research and Manufacturers of America (PhRMA)
  - ✓ Accreditation Counsel for Continuing Medical Education (ACCME)
  - ✓ American Medical Association (AMA)
- Review the risks of not complying with the regulations within the current regulatory/legal environment:
  - ✓ Fines, Exclusions, Incarceration, Damage to Reputation
- Apply the guidelines, rules, and policies to the development and execution of PRM materials, formats, and programs

## PRM Program Components

### Tactical Implications of Patient Relationship Marketing

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

### Questions Addressed

- 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 the 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?
  
- **Note:** Course Content is divided into 3 one-hour sessions containing lecture material and a Q&A segment. The sessions correlate to the three sections of the **Regulatory Compliance Test (RCT) for Patient Relationship Marketing:**
  - **Regulatory Compliance 101: Patient Relationship Marketing Part I** – Addresses Basic RCT-A
  - **Regulatory Compliance 101: Patient Relationship Marketing Part II** – Addresses Basic RCT-B and Advanced RCT
  - **Regulatory Compliance 101: Patient Relationship Marketing Part III** – Addresses both RCT levels through case studies

### **Course Instructors**

Nationally recognized experts on regulatory aspects of healthcare advertising and promotion, both formerly with the Food and Drug Administration (FDA).

#### **Wayne Pines**

*Chair of the CCC Advisory Board.* He is a nationally recognized expert on regulatory aspects of healthcare advertising and promotion. Wayne served at the FDA for 10 years as chief of consumer education and information, chief of press relations, and associate commissioner for public affairs.

#### **Michael Misocky**

President of Misocky Consulting Group. Former Regulatory Review Officer for FDA Division of Drug Marketing, Advertising, and Communications (DDMAC). Formerly Assistant VP and Deputy Compliance Officer at ImClone Systems; also worked at Abbott Labs and Bristol-Myers Squibb.

### **CCC's Regulatory Compliance Test (RCT)**

CCC certifies regulatory competency in Patient Relationship Marketing at two levels: **Basic** and **Advanced**. The **Regulatory Compliance Test (RCT)** for Patient Relationship Marketing is structured in three sections:

**Basic RCT-A:** Patient Relationship Marketing Regulatory Environment

**Basic RCT-B:** Tactical Implications of Patient Relationship Marketing

**Advanced RCT:** Patient Relationship Marketing Scenarios