

# CCC Training and Mastery Testing

## I. CCC MISSION

The Center for Communication Compliance (CCC) is the only all-in-one global source for training, certification, and consulting in **healthcare regulatory compliance** and **risk communication** that:

- ▶ Provides customizable and off-the-shelf tools and systems needed to deliver compliant materials and programs in 45 countries around the world
- ▶ Delivers job-relevant, accurate, up-to-date content on-demand through Web-based coursework, available to the industry 24/7
- ▶ Establishes consistent standards for regulatory mastery through a proprietary Train + Test competency method
- ▶ Administers the only expert-validated tool to confirm employees have mastered fundamentals of regulatory compliance (similar to SAT and the Stanley Kaplan Test Prep)
- ▶ Provides a suite of consulting services from international experts (see pages 8-9 in Section IV for CCC Advisory Board, which includes former FDA officials, JDs and other regulatory/legal experts)



## II. PRODUCT OVERVIEW

---

Regulatory Compliance coursework is available in four disciplines: advertising/promotion, promotional medical education, public relations, and patient relationship marketing. The content is granular and addresses tactics executed to promote drugs and devices. CCC offers training and tests in 45 countries.

<p><u>Advertising</u></p> <ul style="list-style-type: none"><li>✓ Sales aids</li><li>✓ DTC advertising</li><li>✓ Coming soon ads</li><li>✓ Reminder ads</li><li>✓ Institutional and disease awareness ads</li><li>✓ Comparative claims and claims of superiority</li><li>✓ Web sites</li><li>✓ Exhibits</li></ul> <p><u>Promotional Medical Education</u></p> <ul style="list-style-type: none"><li>✓ Speaker's Bureaus</li><li>✓ Presentations at scientific meetings</li><li>✓ Contractual arrangements</li><li>✓ Publication plans</li><li>✓ Speakers' fees</li><li>✓ Slide kits</li><li>✓ Gifts to physicians</li><li>✓ Social events and sponsorships</li><li>✓ Mechanism of action (MOA) and other videos</li></ul>	<p><u>Public Relations</u> Investigational &amp; marketed products)</p> <ul style="list-style-type: none"><li>✓ Press releases</li><li>✓ Press packs</li><li>✓ VNRs, B-Roll</li><li>✓ Media tours</li><li>✓ Web sites</li><li>✓ Webcasts</li><li>✓ Spokespeople</li><li>✓ Media training</li><li>✓ Consultancy</li><li>✓ Clinical Trial Recruitment</li></ul> <p><u>Patient Relationship Marketing</u></p> <ul style="list-style-type: none"><li>✓ Interactive Design</li><li>✓ Content Development &amp; Copy Strategy</li><li>✓ Brand Integration</li><li>✓ Relationships with Third-party Groups</li><li>✓ Patient Consent &amp; Privacy</li></ul> <p><u>Internet Marketing and Social Media</u></p> <ul style="list-style-type: none"><li>✓ All tools</li></ul>
---	---

See Examples of Questions Addressed on Pages 5 – 8 in Section III.

### **Regulatory Compliance 101 Training: North America**

The North American Regulatory Compliance 101 training series is comprised of Web-based training seminars taught by nationally recognized regulatory experts. Regulatory Compliance 101 is available in advertising/promotion, patient relationship marketing, promotional medical education, and/or public relations (PR).

**Training Module I (1 HOUR)** – Reviews regulations/policies/guidelines established by government agencies, industry groups

**Training Module II (1 HOUR)** – Reviews development and execution of programs/materials within regulatory guidelines

**Training Module III (1 HOUR)** – Provides case study-based learning using complex, multi-factorial scenarios.

The 3 one-hour sessions, containing lecture material and a Q&A segment, correlate with the Regulatory Compliance Tests (RCTs). Just as the Stanley Kaplan Test Prep program prepares students for the SAT, the Regulatory Compliance Tests (RCTs) are correlated with the CCC series of compliance training modules to prepare participants for the tests.

The course curriculum can be found [here](#).

**BASIC PUBLIC RELATIONS REGULATORY COMPLIANCE TEST**

Question 9 of 20: previous next 1 of 20 questions answered SUBMIT ANSWERS

Which statements about Video News Releases (VNRs) for products still under investigation are generally consistent with FDA policy? (check the 2 answers that are true)

- New research results but not conclusions about safety and efficacy for products that are still being investigated can be discussed in a VNR
- If studies have been completed and published in a peer-reviewed journal that demonstrate efficacy, the VNR may say that the product has been found to be effective
- The VNR should include a disclaimer to the effect that the product is not approved and is currently under investigation
- The VNR must be reviewed by the FDA before issuance
- The FDA prohibits companies from issuing VNRs for products still being investigated

Correlation model similar to SAT/Kaplan Test Prep

**General Regulatory Considerations**

Press materials that are product-related would be considered by FDA (DDMAC) to be promotional labeling

- Press releases
- Video news releases (VNRs)
- Radio news releases (RNRs)

8

## Regulatory Compliance 101 Training: Ex-U.S.

The Global Regulatory Compliance 101 coursework is available in 44 countries plus the U.S. Each country's program combines training and certification and is administered 24/7 from the CCC web site. The modules vary in length by country and are taught by internationally recognized regulatory experts. The full curricula with complete listing of available countries (see [here](#)) covers:

- Regulatory Environment
- Difference Between Promotion and Non-Promotion
- Promotional Execution
- Handling Unsolicited Requests
- Dealing with Healthcare Professionals
- Off-Label Promotion/Scientific Discussion
- Public Relations: Trade, Consumer, Events
- Internet/Social Media
- Communications with Patients
- Devices
- Compliance Programs and Training

## CUSTOM TRAINING

CCC also custom-designs training and certification LMS (Learning Management Systems) programs with increased interactivity, drag-and-drop testing, embedded quizzes, and "do's and don'ts" for compliance policies and guidelines. CCC can convert content to conform to SABA eLEARN, SumTotal, Moodle, or any custom-designed LMS system. The company is familiar with the various eLearning standards for LMS systems, including SCORM 1.2, SCORM 2004, and AICC.



**Regulatory Certification Test: Confirming Mastery of Critical Regulatory Information**

All CCC Regulatory Compliance Tests have been designed by education and test-construction experts. RCTs correlate with the CCC Regulatory Compliance 101 Training series and are customized to each respective communication discipline (e.g., ad/promo, promo med ed, patient relationship marketing, public relations, etc.).

Mastery test development is an intensive process that includes multidisciplinary input from CCC Advisory Board members and experts in Compliance, Regulatory, Legal, Communications, and Test Construction. Questions and their answers are updated based on changes in the regulations.

Students receive a certificate of completion once an 80% passing score is achieved. CCC reporting mechanisms can be as comprehensive and detailed as desired.

**Handling Internal Training From a Macro Perspective**

CCC understands the importance of communicating information about regulatory developments and related marketplace trends to internal stakeholders. Given that, we have the ability to provide relevant content using diverse delivery mechanisms.



---

### III. EXAMPLES OF QUESTIONS ADDRESSED BY CCC TRAINING AND TESTING SYSTEM

---

#### 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?

### 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, and Brand Integration
  - ✓ 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?
  - ✓ 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?
- 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?

#### Internet Marketing and Social Media

- Regulatory Environment
  - ✓ What government agencies oversee this medium and what are the penalties for noncompliance?
- Macro Questions
  - ✓ How can you promote prescription products online these days with all the limiting regulations? What can you really do in social media that is not violative of FDA DDMAC regulations? Said another way, which social media strategies can be implemented that are in compliance with FDA regulatory framework?
  - ✓ What are the regulatory implications of the specific space and time limitations inherent in the various social media channels? How do these constraints affect online marketing today and what new issues may raise from a regulatory perspective?
  - ✓ FDA has guidelines about format/layout/typography/white space in regard to print ads ... how will these “implementing factors” play out in social media and Web sites, which are so different from print?
- Tactical Questions
  - ✓ What guidelines exist with respect to positioning fair balance relative to claims on the Internet? What does the FDA consider adequate support for promotional claims?
  - ✓ What are the regulatory issues affecting branded vs. unbranded online sites?
  - ✓ What is **one-click rule**? What are the implications for Internet-based promotion?
  - ✓ What kind of external websites can we link users to in order to provide additional reference materials? Are there potential risks with such links?
  - ✓ What are the regulatory considerations surrounding Search Engine Optimization (SEO) techniques and tactics, such as meta tags?
  - ✓ What happens if a product is mentioned on a disease awareness chat room sponsored by the drug or device company? What opportunities does the company have to augment and/or correct information? How should this information be handled?
  - ✓ Do you have to scroll the full package insert on every video that a patient might link to? Does it have to be in the front of the video or can risk information be integrated throughout the communication?

- ✓ What do I have to know about prescription products with boxed warnings? What about a product under accelerated approval fast track?
- ✓ What do I need to know about selecting patient testimonials for online use? Do they need to represent "the typical patient"? What precisely does this phrase mean?
- ✓ What FDA regulations need to be adhered to when using patient testimonials (i.e., Quality of Life claims/statements)
- ✓ What are the policies and guidelines regarding the use of spokespersons in social media? If I use a celebrity, does he/she have to have the disease? What if I only use their name and picture, but without any statement or testimonial?
- ✓ Does the FDA have any guidance about having to post your press releases on your Web site? Or how long you should keep them available to the public/physicians/investors? Can you be cited for not posting them?
- ✓ Are there specific regulatory considerations regarding the "Investor Relations" section of a company's Web site? What can you say/not say to investors about drugs currently under development?

## IV. CCC Advisory Board

---

### Regulatory and Legal Experts

**Wayne Pines** is the 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. He is the author of the two-volume *FDA Advertising and Promotion Manual*, the standard reference in the field, and chairs the annual advertising and promotion conferences sponsored by the Food and Drug Law Institute (FDLI) and the Drug Information Association (DIA), among others.

Board members who provide insight on or instruct CCC offerings include:

- ▶ **Tracy Acker, PharmD:** President at The Acker Consulting Group: Served as Branch Chief in FDA's Division of Drug Marketing, Advertising and Communications (DDMCA); Former Executive Director of Regulatory Promotion at Amgen and Johnson & Johnson
- ▶ **Lewis Amsel, PhD:** President at Pharmaceutical Consulting Services, Inc.; Served as Executive Director of Worldwide Pharmaceutical Technology at Searle/Pharmacia/Pfizer; Former VP of Pharmaceutical Technology at Watson Pharmaceuticals
- ▶ **Alan Bennett, JD:** Managing partner of Ropes & Gray, Washington, D.C. Served in FDA General Counsel's Office. Former legislative assistant to the late Sen. Jacob Javits and Counsel to the Senate Governmental Affairs Committee.
- ▶ **Glenn N. Byrd, MBA, RAC:** Director of Regulatory Affairs at MedImmune. Spent 10 years at FDA. Was Chief of the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Research (CBER).
- ▶ **Carolyn Choh:** Professor at St. Joseph's University Executive Pharmaceutical MBA Program; Currently serves on admissions committee of Executive Pharmaceutical MBA program at SJU; Serves as advisor to Masters Int'l Marketing (MIM), Pharmaceutical Leaders of Tomorrow
- ▶ **Mark E. DuVal, JD:** President of DuVal & Associates. Previously, in-house FDA, Anti-Kickback, and False Claims Act expert for Medtronic.
- ▶ **Arnie Friede:** Principal at Arnie I. Friede & Associates. Served as Associate Chief Counsel in FDA's Chief Counsel Office. Former Senior Corporate Counsel at Pfizer, Inc., and former Chairman of Food, Drug, & Cosmetic Law section of NYS Bar Association.
- ▶ **Tony Iacono:** President, Access Medical Network. Formerly Assistant VP, Wyeth Pharmaceuticals, Chair of Promotional Guidelines Committee; Former member of AMA's Working Group on Gifts to Physicians from Industry

- ▶ **Dr. John F. Kamp:** Executive Director of the Coalition for Healthcare Communication and of counsel with law firm Wiley Rein. Ten years in Washington, DC office of the American Association of Advertising Agencies. Formerly in public policy positions at the Federal Communications Commission.
- ▶ **Ahmet Karayazgan:** Managing partner at Karayazgan Law LLP; Formerly in-house counsel for several multinational companies including Mobil, Allianz, and Fortis Insurance in Turkey; Specializes in malpractice, hospital liability, and liabilities arising out of clinical trials
- ▶ **Coleen Klasmeier, JD:** Partner in Sidley Austin's Life Sciences Practice. Author of two-volume *FDA Advertising and Promotion Manual*. Former Special Assistant to Chief Counsel at the FDA.
- ▶ **Maurits J. F. Lugard:** Partner, Sidley Austin LLP Brussels office, EU Life Sciences Regulatory team leader. Nine years at European Commission, including three years at their Legal Service; six years at the European Commission's Directorate-General for Enterprise. Led EU's "de-regulation" efforts in Japan for EU industrial products, including drugs and medical devices.
- ▶ **Alan Minsk, JD:** Partner and Chair of Food & Drug Practice Team of Arnall Golden Gregory. Currently General Counsel of the PDMA Alliance.
- ▶ **Michael A. Misocky, RPh, JD, CHC:** 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 and BMS.
- ▶ **Nancy Zecco, MPH:** Senior Regulatory Associate at Alkermes, Inc.; Extensive experience at managing regulatory audits of Phase I to IV clinical trials

### Education and Testing Advisor

**Dr. Lester Hoffman** is a nationally recognized expert in test construction and educational standards quality control. He has created certification and mastery tests and developed training programs on Regulatory Compliance in pharmaceuticals, financial services, and other regulated industries. Clients have included Novartis, Pfizer, Eli Lilly, Novo Nordisk, Avon, Bank of America, JP Morgan/Chase, Lockheed-Martin, FedEx, and AT&T. Dr. Hoffman has also designed and evaluated many Web-based training programs for baseline competencies in regulated industries.

Dr. Hoffman has a PhD from Harvard University, where he did advanced academic research and graduate teaching in Instructional Design and Cognitive Psychology. This, combined with his 25 years of business experience, has enabled Dr. Hoffman to apply in business settings the principles of human learning and educational testing. At AT&T and Bell Labs, where the disciplines of mastery testing and competency models were first established in American industry, he worked with the pioneers of educational testing quality control and skill modeling.

### Communications Expert

**Ilyssa Levins, founder and president**, is a 30-year communications veteran who spearheaded growth for Grey Global Group, one of the world's foremost communications firms, over a period of two decades. A Phi Beta Kappa NYU graduate, Ilyssa's entrepreneurial accomplishments included launching the BrandEdge marketing consultancy, catapulting Grey's healthcare public relations (PR) practice to a top 10 global ranking, and leading a PR boutique, GTFH, to be named #1 in healthcare two years in a row. In 1991, she founded the PR section of the Coalition for Healthcare Communication, an industry advocacy group focused on FDA regulatory policy and enforcement. Ilyssa was the only healthcare executive to be named a Women Achiever of the Year by the YWCA of New York for the class of 2000, and is a Healthcare Businesswomen's Association (HBA) Rising Star. Her Board memberships include the HBA, where she served two terms as Director of Marketing Communication and where she is currently Director-at-Large, Business Development and Strategic Alliances.