

## About CCC

CCC is the only all-in-one global source for training, certification, and consulting in **healthcare regulatory compliance** and **risk communication**. The company's mission is to reduce risk, save time, and increase industry credibility through **education**, **expertise**, and **standardization**.

CCC:

- ▶ Provides the country-specific knowledge and tools needed to deliver compliant and strategic counsel
- ▶ Delivers job-relevant, accurate, up-to-date content
- ▶ Establishes consistent standards for regulatory mastery through our proprietary competency model
- ▶ Makes on-demand, Web-based coursework available to the industry 24/7
- ▶ Provides a suite of consulting services from world-class experts

Today's rapidly evolving regulatory environment requires that pharmaceutical, biotech, and medical device professionals around the world achieve excellence in regulatory compliance and risk communication. CCC meets this critical need – from drug development to sales and marketing. Our commitment is to save time, reduce risk and increase the industry's credibility.

The company's expert **Advisory Board** is composed of leaders in FDA regulations, government guidelines, and voluntary industry codes, and includes former FDA officials and regulatory lawyers in pharmaceutical and medical device companies and from independent consulting and law firms.

### “CONTINUUM OF LEARNING” APPROACH: TRAINING PLUS CERTIFICATION

CCC has a unique approach to regulatory compliance training, which we refer to as a “Continuum of Learning.” Specifically, we use our expert-developed and reviewed certification tests to uncover or diagnose knowledge gaps. Coursework is then matched to the individual's knowledge level. The certification tests are then used to confirm that the staffer has mastery over the information. The tests can also be used to monitor competence on a yearly basis.



# Off-the-Shelf Regulatory Compliance Education Available Online

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## **U.S. PROMOTIONAL TRAINING AND CERTIFICATION 101**

CCC offers Web-based regulatory compliance training seminars taught by nationally recognized regulatory experts. The modules cover five distinct disciplines: advertising/promotion, promotional medical education, public relations, patient relationship marketing, and Internet promotion and social media. The course content is customized for each discipline and addresses 1) regulations, policies and guidelines established by government agencies and industry groups; 2) development and execution of programs/materials within regulatory guidelines; and 3) complex, multi-factorial scenarios in a case-based format, with in-depth discussion. Online coursework is available in 45 countries (see page 8).

The Regulatory Compliance Test (RCT), which directly correlates with the Regulatory Compliance 101 training, certifies competency at two levels: Basic and Advanced. Each RCT covers Regulations and Policies, Materials, and Scenarios in its specific discipline. Every CCC Regulatory Compliance Test (RCT) is reviewed by leaders in the fields of healthcare communication compliance, education, and test construction.

## **REQUIREMENTS FOR COMPANY SPOKESPEOPLE**

CCC offers a Web-based tutorial on the regulatory guidelines for individuals who will be speaking on the company's behalf, whether they are investigators recruiting patients for clinical trials, physicians embarking on a media tour or being filmed for a promotional video, or medical experts preparing to address a group of investors. This concise overview of the do's and don't's related to promotion of marketed drugs or the exchange of scientific data for investigational products puts everyone on the same baseline when embarking on a communications program.

## **GLOBAL COMPLIANCE COURSEWORK**

Regulatory Compliance 101 is also available in 45 countries (see list on page 8). Products available include:

- **Module 1 Training:** Application/Dossier Submission & Approval
- **Module 1 Expanded Training:** Approval of Promotional Materials by Regulatory Authorities
- **Module 2 Training & Certification:** Global Promotional Compliance

The length of each module, taught by regulatory experts, varies by country. Certification is available. Training and certification tests can also be purchased with local market translations. Online coursework is available in 45 countries (see page 8).

## **DRUG DEVELOPMENT 101**

This one-hour module with corollary certification is directed to professionals starting out in the pharmaceutical and biotech industries or professionals new to healthcare (e.g., a digital specialist who joins a company engaged in drug or device product development/marketing). The coursework covers the drug development process, including an overview of a drug's life cycle from discovery through post-marketing studies. It also addresses at a basic level the pre-clinical and clinical phases, and provides easy-to-understand definitions for commonly used terms in the drug development process.

## Customized Training and Consulting

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### **LIBRARY OF CERTIFICATION QUESTIONS**

This offering is designed to increase the effectiveness and return on investment of in-house regulatory compliance training programs by validating that employees have mastered the information. CCC develops mastery testing for companies by accessing its unique library of more than 300 expert-validated test questions and answers that reflect what government laws, regulations, policies, and voluntary industry codes require. The questions are based on a consensus perspective of experienced experts, including former government officials and legal/ regulatory experts.

For companies with an existing regulatory compliance training curriculum *without* mastery testing, CCC will customize a group of test questions/answers that correlate with existing training content. This will include establishing the optimal test length and sequence of questions, and provide the scoring system, question configuration (e.g., true/false, multiple choice, case study-based), and number of answer options per question.

Companies with already developed test questions benefit from expert analysis, which validates that existing questions and answers are consistent with federal regulations and company policies. This also determines whether the questions themselves are adequate and comprehensive enough to determine "competency" in a given regulatory area.

### **COMPANY-COMPLIANT LMS CONTENT**

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

### **RISK SENSITIZATION WORKSHOP**

This workshop helps compliance and regulatory professionals within a company align their internal stakeholders (R&D, clinical, marketing, communications). This ensures better understanding of, and compliance with, regulatory and safety considerations that must be evaluated and addressed during the drug development continuum. The workshop seeks to educate participants on the implications of risk assessments and risk management and the consequences of failing to accommodate to changes in the environment. This session will create a common understanding among a company's various internal stakeholders of the current requirements and regulatory/enforcement environment, and underscore why internal collaboration helps to ensure successful product development and approval. Throughout the exercise, various ways of managing the lifecycle of a product will be evaluated in the context of the new regulatory requirements, leading to an understanding of how to comply while still achieving business objectives.

### **RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

Throughout a brand's life cycle, a continuum of strategy and execution is needed to satisfy the requirements of Risk Evaluation and Mitigation Strategy (REMS), a new communications provision provided for in the FDA Amendments Act (FDAAA) of 2007. CCC helps ensure that risk information is communicated effectively and proactively, and that systems are in place to ensure compliance. This includes counsel/execution in regard to REMS creation, research, education, preparedness planning, and organizational development. CCC can provide additional detail on these offerings under separate cover.

## Consulting and Diagnostics

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CCC regulatory and legal experts, many of them former FDA officials, are available to consult on diverse topics and issues, or to support a company's interaction with the FDA. This includes an analysis of marketing initiatives to assess risk associated with promotional or educational strategies and specific tactics. CCC also audits the internal processes of companies and develops customized recommendations for creating a culture of compliance throughout the organization. This includes recommendations to strengthen the review procedure prior to submission of materials, compliant use of e-mail, and a version control process for program recommendations.

CCC can also help you assess the cost of non-compliance from redos of violative materials. See: <http://www.theodolitehc.com/tmp/cost-of-noncompliant-teams-industry.html>.

## CCC Advisory Board

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**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 training and certification tests are:

- ▶ **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).
- ▶ **Tom Chakraborti:** Attorney with Sidley Austin LLP Brussels office, specializing in pharmaceutical law, including regulatory compliance. Trained as a physician and then as a solicitor at the international law firm, Slaughter and May. Has held a global position with Novartis as Senior Legal Counsel and an international position at Gilead Sciences Europe Ltd, as a Director in its international legal department.
- ▶ **Mark E. DuVal, JD:** President of DuVal & Associates. Previously, in-house FDA, Anti-Kickback, and False Claims Act expert for Medtronic.
- ▶ **Tony Iacono:** President, Access Medical Network. Previously, Assistant VP, Wyeth Pharmaceuticals, and 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.
- ▶ **Coleen Klasmeier, JD:** Partner in Sidley Austin's Life Sciences Practice. Author of the two-volume *FDA Advertising and Promotion Manual*. Former Special Assistant to the Chief Counsel at the FDA.

### **Advisory Board (Continued)**

- ▶ **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.

## **U.S. Training Programs: Examples of Questions Covered in Coursework**

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### **Advertising/Sales Promotion**

- ✓ In our advertising, we want to highlight several specific data points from our Phase III clinical study. Would this be considered "cherry picking"?
- ✓ We want to send a letter to physicians claiming that our product is the most prescribed in its class. What data are needed to support this statement?
- ✓ Can we use a competitor's published data in promoting our product?
- ✓ We want to use our product's trade name in a "coming soon" ad. Can/must we use the generic name until we receive FDA product approval?
- ✓ How many of the most common adverse events for a product need to be listed in an ad to ensure that it is fairly balanced? Is there a specific number that the FDA looks for?

### **Promotional Medical Education**

- ✓ Phase III trial data has just become available for a new product under development. What kind of meetings with the experts in the field can be held 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 – are we permitted to pay for their expenses as well? If they meet at resort locations to discuss the latest product data, research, and company plans, is that OK?
- ✓ A key opinion leader speaking on behalf of a company goes off script and tells the audience about an unapproved use. What is the obligation of a company or agency representative in that circumstance?
- ✓ 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 labeling. Should the speaker be allowed to share the data, given his/her expertise and the fact that the data are published in a top journal?
- ✓ 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?

## Public Relations/Advocacy 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 if the physicians think that the product is superior to competing treatments – are there any “watch-outs”?
- ✓ A product is already approved for one indication, but this study is investigating 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 after such a meeting?

## Patient Relationship Marketing

- ✓ What are guidelines for developing patient-directed copy for disease awareness sites?
- ✓ When can we use market research data in a promotional campaign?
- ✓ Does the FDA prohibit companies from dealing with patient groups? Does 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?
- ✓ 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 be in place?

## Internet Promotion and Social 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?

# Global Training Programs: Examples of Questions Covered in Coursework

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## Compliance Module 1: Application/Dossier Submission & Approval

- ✓ What is a typical time frame between application/dossier submission and approval?
  - ✓ Are advisory committees ever held prior to approval, and if so, in what situations?
  - ✓ Are there different types of "decision letters" issued by the regulatory agency?
  - ✓ What role, if any, does cost-effectiveness data play? Is this ever required in an application/dossier?
  - ✓ What is the term for "prescribing information" or "labeling" in this country? What is included in the prescribing information?
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## Compliance Module 1 EXPANDED: Approval of Promotional Materials by Authorities

- ✓ Is there an outside agency that reviews promotional material or is that done by the same regulatory agency that reviews applications/dossiers? If it is a different agency, what is its name?
  - ✓ Do all promotional materials need to be submitted in advance of actual use, and if so, how much in advance must they be submitted? Are there exceptions, i.e., may some materials be used prior to approval by the agency?
  - ✓ What is the time frame for approvals, if required?
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## Compliance Module 2: Global Promotional Compliance

- ✓ What laws and codes of practice govern the advertising of medicinal products in this country? Which government/regulatory agencies oversee company compliance?
- ✓ How is advertising and promotion defined in this country?
- ✓ Are there regulations or guidelines regarding interactions between industry representatives and healthcare professionals? If so, what are they?
- ✓ Are there any specific regulations that are important to note regarding off-label use of a drug/biologic/device?
- ✓ What are the regulations, if any, regarding the distribution/use of reprints by industry representatives?
- ✓ Are there specific regulations regarding the appearance of promotional materials, for example, font size/formatting of words/messages, use of artwork, message placement, etc.?
- ✓ Can companies pay for reporters to attend press events?
- ✓ How is Internet advertising regulated? What are the rules?

## Countries Currently Available

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|-----------------------|----------------------|
| <b>Argentina*</b>     | <b>Japan</b>         |
| <b>Australia</b>      | <b>Korea</b>         |
| <b>Austria</b>        | <b>Latvia</b>        |
| <b>Belgium</b>        | <b>Lithuania</b>     |
| <b>Brazil</b>         | <b>Luxembourg</b>    |
| <b>Bulgaria</b>       | <b>Malaysia</b>      |
| <b>China</b>          | <b>Mexico</b>        |
| <b>Colombia</b>       | <b>Netherlands</b>   |
| <b>Croatia</b>        | <b>Norway</b>        |
| <b>Czech Republic</b> | <b>Portugal</b>      |
| <b>Denmark</b>        | <b>Romania</b>       |
| <b>England</b>        | <b>Russia</b>        |
| <b>Estonia</b>        | <b>Slovakia</b>      |
| <b>Finland</b>        | <b>Slovenia</b>      |
| <b>France</b>         | <b>South Africa</b>  |
| <b>Germany</b>        | <b>Spain</b>         |
| <b>Greece</b>         | <b>Sweden</b>        |
| <b>Hungary</b>        | <b>Switzerland</b>   |
| <b>Iceland</b>        | <b>Turkey</b>        |
| <b>India*</b>         | <b>Ukraine</b>       |
| <b>Ireland</b>        | <b>United States</b> |
| <b>Israel</b>         | <b>Venezuela</b>     |
| <b>Italy</b>          |                      |

\* Custom Pricing