

## CENTER FOR COMMUNICATION COMPLIANCE LAUNCHES REGULATORY COMPLIANCE COURSEWORK FOR MEDICAL DEVICE INDUSTRY

*Up-to-date educational tools help prevent violations and protect companies  
as regulations continue to tighten*

**NEW YORK, May 20, 2010** – The Center for Communication Compliance (CCC) unveils today a comprehensive, on-line training and testing program focused on medical device promotion, as part of its suite of affordable regulatory compliance educational products.

CCC compliance training programs and mastery tests help device companies and their promotional vendors stay ahead of the complicated regulatory environment as government continues to aggressively step up oversight and enforcement. CCC is the only all-in-one global source for training, testing, and consulting in healthcare regulatory compliance and risk communication.

Recent remarks by officials in FDA's Center for Device and Radiological Health (CDRH) indicate that the Agency will be stepping-up oversight of post-marketing practices for medical devices. Government regulations and industry guidelines require that promotional materials should be accurate and not misleading, and consistent with all current regulatory requirements. Any person or organization engaged in device promotion is at risk and accountable, including vendors providing marketing and communication services to the industry.

Wayne Pines, former FDA Associate Commissioner for Public Affairs and chair of the CCC Advisory Board, states, "Compliance officers in device companies need to be sure that all product promotion is compliant, including communications created or executed by the promotional agencies working for their company. Failure to ensure that their communication agencies are properly trained puts companies at unnecessary risk of noncompliance with federal and state requirements."

### ***Certification, Standardized Training Fill Industry Need***

The CCC coursework, known as **Regulatory Compliance 101**, provides an overview of the regulatory environment (e.g., FDA, OIG, AdvaMed) and all relevant regulations, such as the FDA's *Draft Guidance on Presentation of Risk Information* for product promotion. Content covers guidance on the interaction with healthcare professionals and tactics across the entire marketing mix: advertising/ promotion, promotional medical education, public relations, and direct-to-patient initiatives.

CCC has a companion product called the **Regulatory Compliance Test (RCT)** that confirms knowledge of regulations and voluntary policies and their application to tactical execution. Just as the Stanley Kaplan Test Prep program prepares students for the SAT, the CCC coursework directly correlates with the RCT. Coursework is reviewed by members of the CCC Advisory Board, which includes former FDA officials, regulatory lawyers, and regulatory affairs experts from industry and professional consulting firms.

### ***Prevention and Protection***

CCC educational coursework helps industry prevent violations from occurring by closing gaps in regulatory knowledge. Through employee mastery testing, CCC protects companies by demonstrating a commitment to maximum compliance.

Explains Michael Misocky, former FDA official, industry compliance officer, and CCC Advisory Board member: “Training and certification will factor favorably in a federal investigation because this demonstrates a company’s commitment to doing all they can to maximize compliance.”

### **About CCC**

Founded in 2008, CCC is the only all-in-one source for training, certification, and consulting in healthcare regulatory compliance and risk communication. By establishing industry-wide benchmarks for regulatory compliance competency, its mission is to reduce risk, save time, and increase industry credibility through education, expertise, and standardization. CCC materials, training programs, and tests address current, job-relevant issues and regulatory situations at a granular level and are updated to reflect major regulatory and compliance developments. The company offers training and certification in 45 countries.

A list of promotional agencies participating in CCC training and certification programs can be found at [www.communicationcompliance.com/go/Static/firms](http://www.communicationcompliance.com/go/Static/firms).

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- Visit CCC website: [www.CommunicationCompliance.com](http://www.CommunicationCompliance.com)
- Call CCC: 212-368-9868
- Sample certification tests available for review (email/call to request passcode)