

Webinar on

FDA's Scrutiny of Social Media and Corporate Responsibility

Learning Objectives

- FDA's legal approach to Labeling*
- Individual versus Commercial Free Speech*
- Case studies*
- Correcting off-label statements in social media*
- Corporate Policy*

Off-label promotion falls within the scope of labeling requirements as defined by the Federal Food, Drug, and Cosmetic Act, as amended (FDCA).

PRESENTED BY:

Casper (Cap) Uldriks, through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. He conducted domestic and foreign inspections. He specialized in the FDA's food and medical device programs as a field investigator, served as a senior manager in the Office of Compliance at the Center for Devices and Radiological Health (CDRH) and as the Associate Center Director for Regulatory Guidance and Government Operations at CDRH.

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

Off-label promotion falls within the scope of labeling requirements as defined by the Federal Food, Drug, and Cosmetic Act, as amended (FDCA). FDA's application of labeling requirements to the information posted in social media of any type creates a new field of enforcement opportunity, one that may catch you by surprise. If off-label statements, whether express or implied, end up directly or indirectly in the lap of your corporate responsibility. You need a well-defined corporate policy on how you will manage this ever-evolving and the very public land of danger. To manage the legal issue of off-label promotion of social media, you must understand FDA's legal approach to what is unacceptable labeling, the Constitutional right to the freedom of speech, the limits placed on your "speech" and how you can actively guard against FDA's claim against you for off-label promotion. Using the excuse of, "I had no idea," will not help.



FDA applies standard legal charges for off-label promotion and advertising in social media, a legal drama that did not exist when Congress established FDA's legal charges against false and misleading labeling. Now, FDA's closely follows information of any "off-label" statements, whether made by a firm or an individual citizen. How do you steer clear of labeling requirements and prohibitions in social media?



Who Should Attend ?

All FDA regulated firms

Regulatory Affairs Director

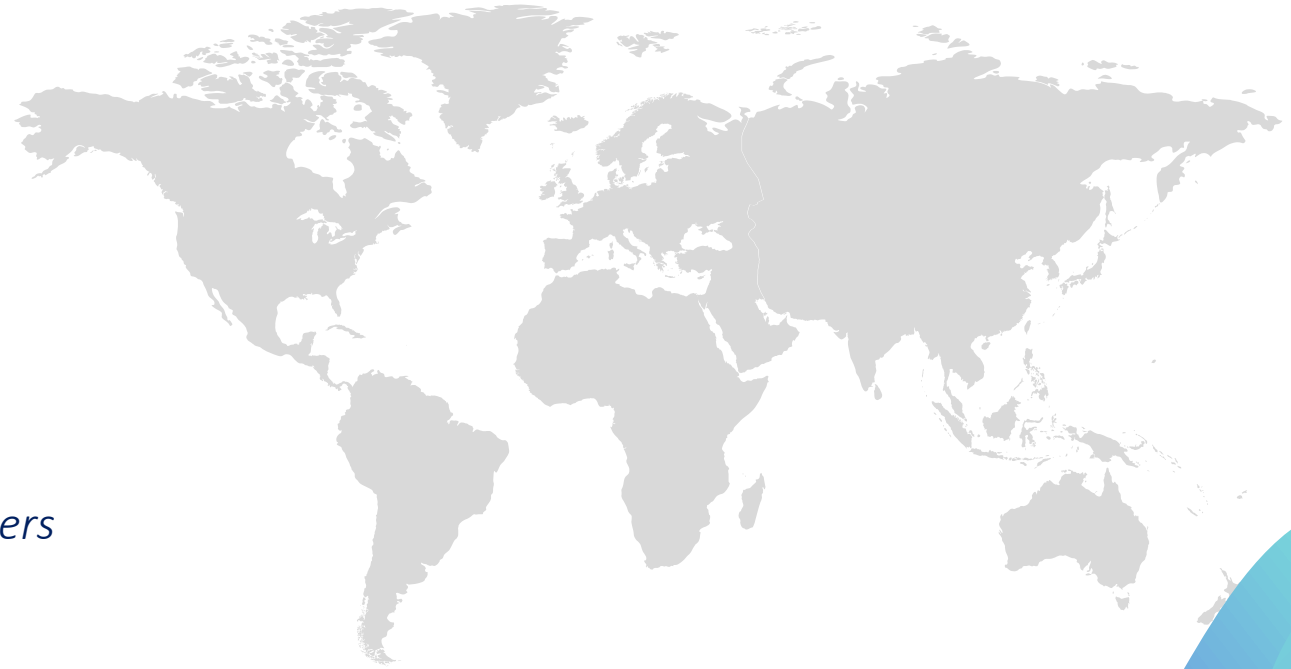
Marketing Director

Quality Assurance Manager

Operations Managers

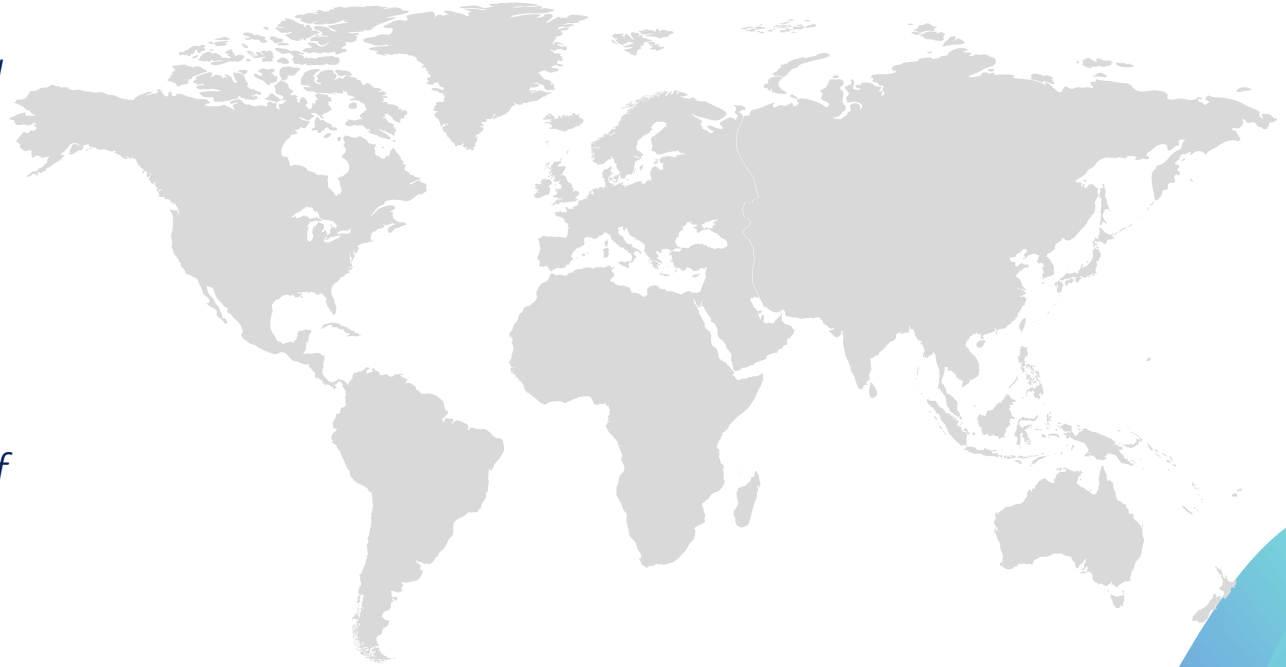
Complaint Department Manager

Human Resources Training Program Managers



Why Should You Attend ?

The scope of FDA's scrutiny of social media throws a wider net than most people realize. Seemingly out of the blue, FDA with legal charges for off-label promotion. How do you plan for that? If you don't know, you are trailing the curve of regulatory obligations. Marketing departments and regulatory affairs departments need to establish a clear and effective program to reign in a firm's vulnerability of intentional and unintentional violations. In some cases, firms are clueless about their violations. How do you protect yourself? Social media places you in the midst of unrestrained freedom of speech for individuals, but the legal boundaries of "commercial free speech" put firms on a very different footing. If you do not know where you stand, you are likely on a dangerous path, somewhat like Hansel and Gretel's journey. The endpoint could be surprisingly disastrous.



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