

Webinar on

BEST SELLER-FDA's Scrutiny of Social Media Off- Label Promotion 6

Learning Objectives

- Scope of Labeling and Claims*
- Constitutional Protection of Commercial Free Speech*
- Social Media Use*
- Direct-to-Consumer Intended Use Problems*
- Corporate Management's Legal Responsibility and Liability*



**FDA's
regulation of
social media
operates as a
moving
target.**

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.

Best Seller

Duration : 60 Minutes

Price: \$150

Webinar Description

FDA's regulation of social media operates as a moving target. What is OK or not OK remains vague, perhaps purposely so. All social media platforms provide an easy common way to cross the FDA's legal boundaries for "misbranding" your product, whether knowingly or unknowingly. In the end, your firm's executive management ends up with the legal responsibility for the enforcement action. A regulatory monster lurks in areas where you fail to take the initiative to check what is being said about your products and how you manage that dynamic of making claims. A failure to include an audit of social media platforms may end up surprising you with an unwelcomed Warning letter from the FDA that explains how you are in violation of FDA law. No one, especially your senior management, wants to be facing a problem with the FDA based on your failure to pre-emptively act on claims made in social media. You need an assertive defense.



FDA regulates how firms advertise and promote their products in social media, which creates a tricky regulatory risk of enforcement action when firms step over FDA's somewhat mysterious advertising and promotion boundaries. What you or someone else says about your product, whether true, false or misleading, becomes a target for FDA's legal hammer. FDA can levy fines, issue Warning Letters and even an injunction or prosecution end up creating a corporate crisis and confusing your customers or driving them away.



Who Should Attend ?

Regulatory Affairs Director

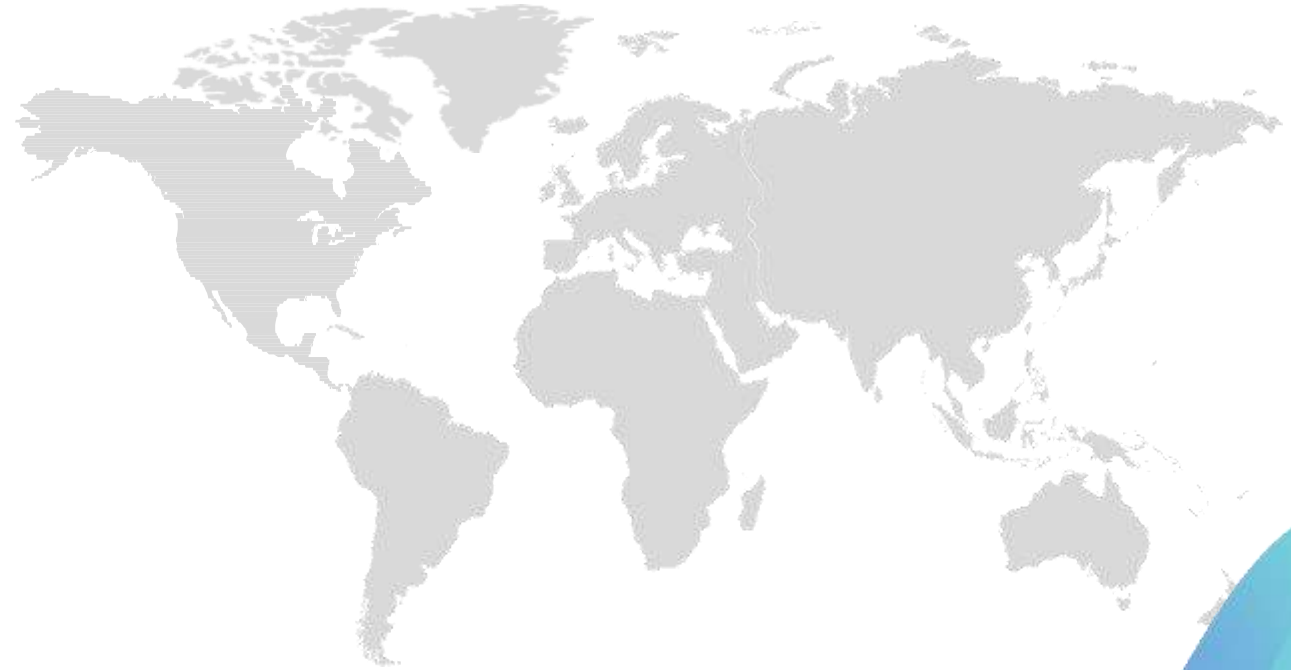
Marketing Director

Quality Assurance Manager

Operations Managers

Complaint Department Manager

Human Resources Training Program Managers



Why Should Attend ?

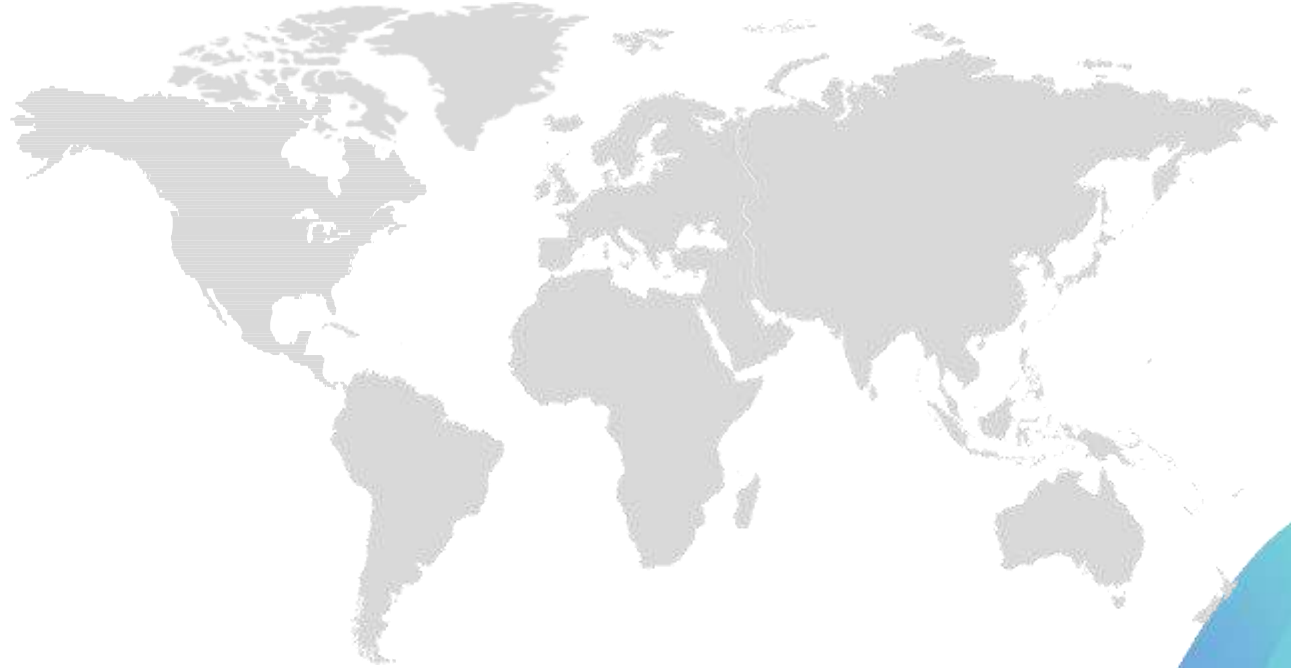
Do you know the difference between what a firm can say and an individual can say without violating FDA law? It can be misleading if you don't

Can your employee's use of social media get their company in trouble? Maybe yes, maybe no

What should your company do about regulatory liability for social media regulatory problems?

What is the legal basis for regulating social media in the first place?

Does Facebook, Instagram, Twitter or any other platform make a difference?



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