GRC Online Training Hub
EDUCATORS
Axona Technology and Solutions

Webinar on

The Risks Embedded in Using Social Media for Product Promotion

Learning Objectives

- *Constitutional Protection of Commercial Free Speech*
- *Scope of Labeling*
- *FDA Policy and Enforcement*
- *Social Media Use*
- *Direct-to-Consumer Intended Use Problems*
- *Education Information Alternatives*
- *Overlapping Federal Laws*
- *Corporate Management's Legal Responsibility and Liability*

What a firm can say in social media and what an individual can say, are two different worlds, but it is easy to jump unknowingly from the individual to the corporate world of what is legally acceptable to FDA.

PRESENTED BY:

Casper (Cap) Uldriks brings over 32 years of experience from the FDA. He started with FDA as a field investigator, worked in the Commissioner's Office for Congressional Oversight Investigations and was the associate Center Director for Regulatory Guidance and Government Operations in the Center for Devices and Radiological Health.

GRC Online Training Hub EDUCATORS
Axens Technology and Solutions

Duration : 60 Minutes

Price: $200

Webinar Description

What a firm can say in social media and what an individual can say, are two different worlds, but it is easy to jump unknowingly from the individual to the corporate world of what is legally acceptable to FDA.

Firms need to extrapolate corporate boundaries for how it can use and not use social media. What a firm says and how firms deliver a message are equally laden with risk. And ripe for FDA'S administrative and regulatory actions. To further complicate the matter, the boundaries for what a firm can and cannot say are not uniform. You need to understand FDA's regulatory approach to avoid the marketing lure that social media creates for illegal off-label use. This begs the question, "Is there legal off-label use?" Regulatory affairs departments and marketing departments need to operate under a strongly supported corporate policy for managing social media. Actually, a corporate policy affects all of the employees that work for a firm and can leave the firm accountable for what employees say on-line. You need to establish and follow well-defined guidelines for yourself.

Who Should Attend ?

Regulatory Affairs Director

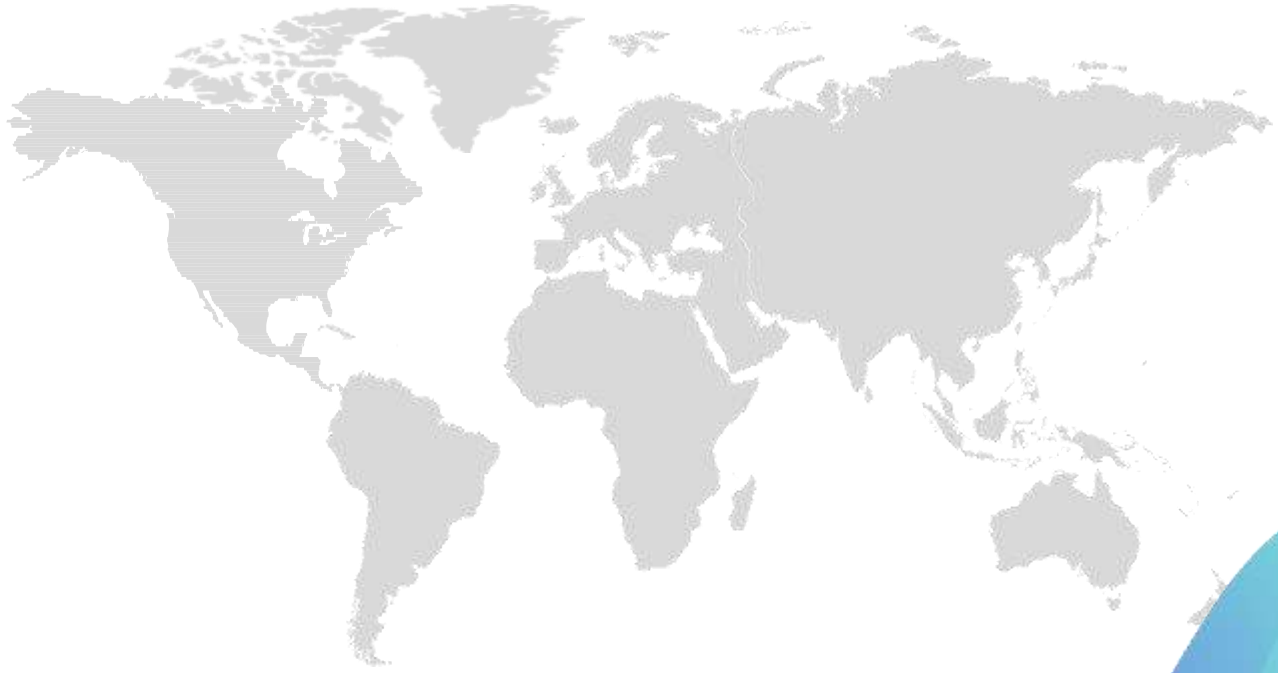
Marketing Director

Quality Assurance Manager

Medical Director

Operations Finance Managers

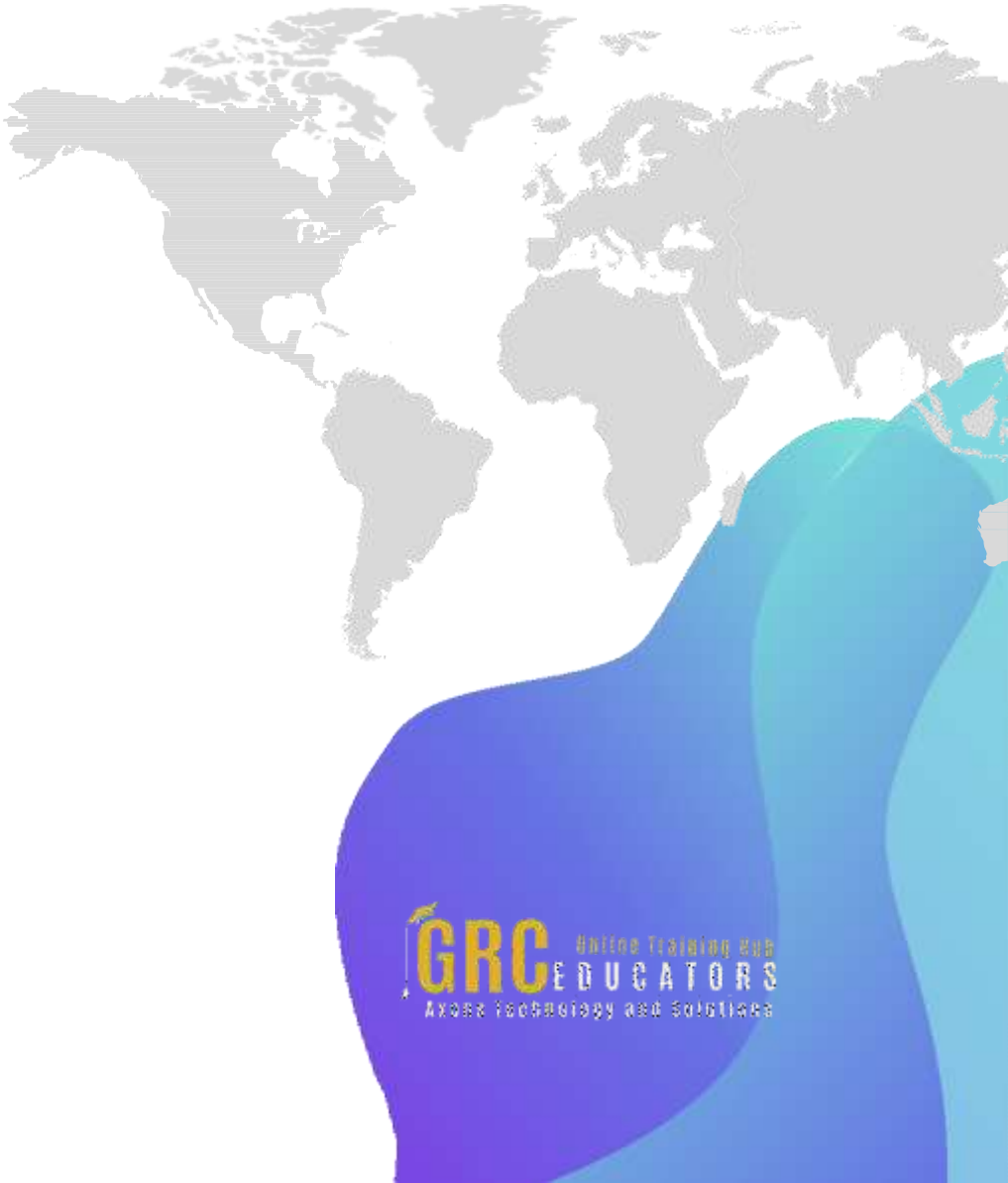
Complaint Department Manager



Why Should You Attend ?

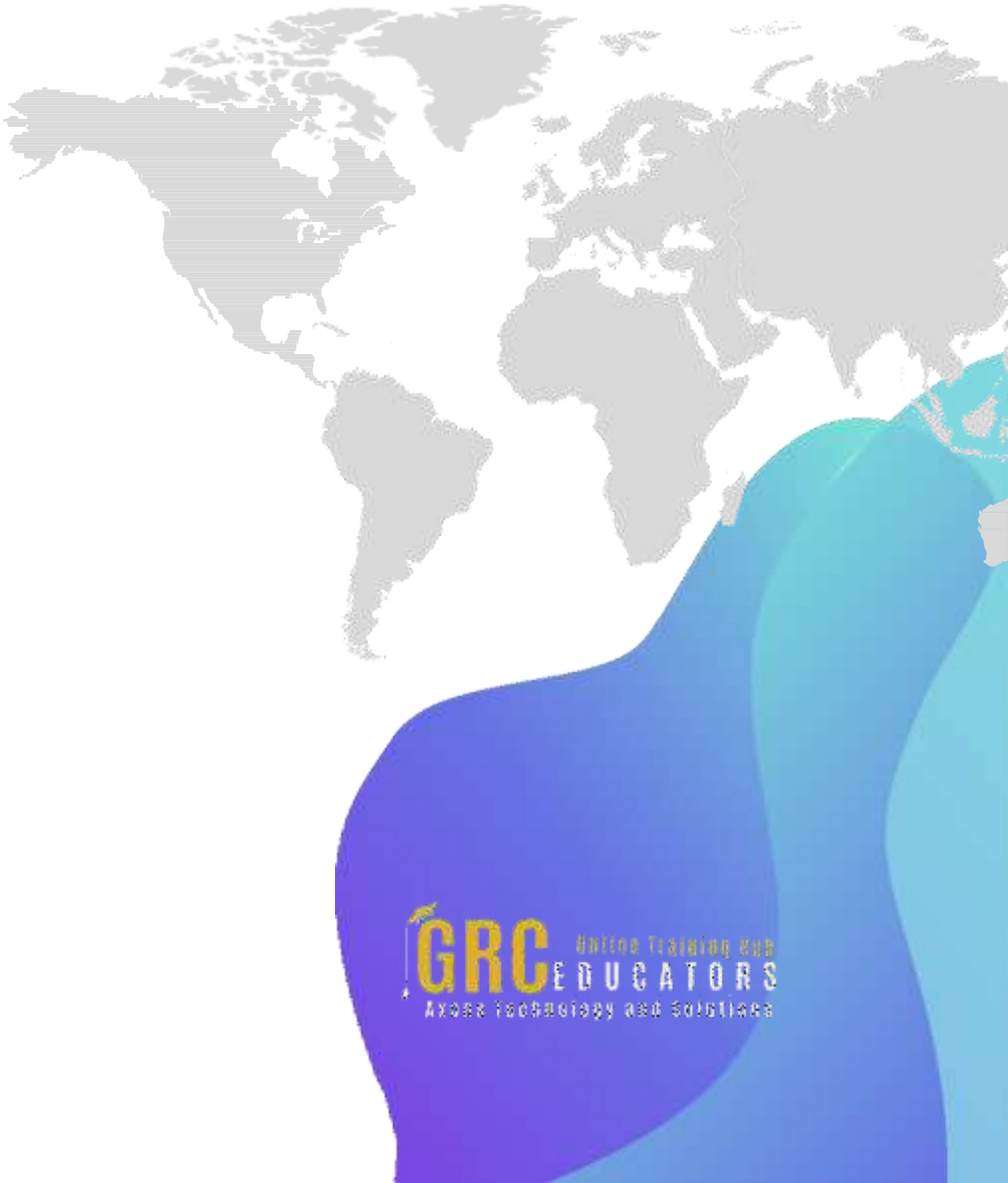
The use of social media provides an easy platform for reaching new and current customers. Social media formats exponentially convey a message that multiples its message delivery, regardless of whether the message is true, false, misleading. Once the message starts, you cannot stop it, only try and correct it. FDA holds a firm accountable for what information it conveys or information leaves out. FDA's regulatory hammer may blindside you because you do not know what has spun out of your control. This is a comparatively new area for labelling enforcement that thrives in a grey area of FDA regulation. Firms must develop and implement a program with specific procedures to stay within regulatory boundaries. What a firm can say and what an individual can say, are two different worlds, but it is easy to jump unknowingly from the individual to the corporate world.

You need to extrapolate boundaries base on FDA'S administrative and regulatory actions. To further complicate the matter, the boundaries for what you can and cannot say are not uniform. What you can say in one part of the country is not permitted in other parts of the country. You need to understand FDA's regulatory approach to avoid the lure that social media creates for illegal off-label use. This begs the question, "Is there legal off-label use?"



Topic Background

FDA regulates how firms promote their products in social media. It creates a regulatory risk for enforcement action when firms step over FDA's somewhat mysterious legal boundaries for advertising and promotion. What you or someone else says about your product, whether true, false or misleading, can become a target for FDA's legal hammer. FDA can levy fines, issue Warning Letters or worse. Such a corporate blunder confuses your customers and may drive them away. Corporate management is accountable and ends up paying an avoidable monetary expense and smear on its corporate face.



To register please visit:

www.grceducators.com

support@grceducators.com

740 870 0321