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Webinar on

BEST SELLER-Fatal FDA Inspection Mistakes

Learning Objectives

- *Inspection Preparation and Policy*
- *Inspection Techniques*
- *Refusals*
- *Human Factors*

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When FDA shows up at your door to announce an inspection, what do you think is going to happen? More importantly, what are you going to do?

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.

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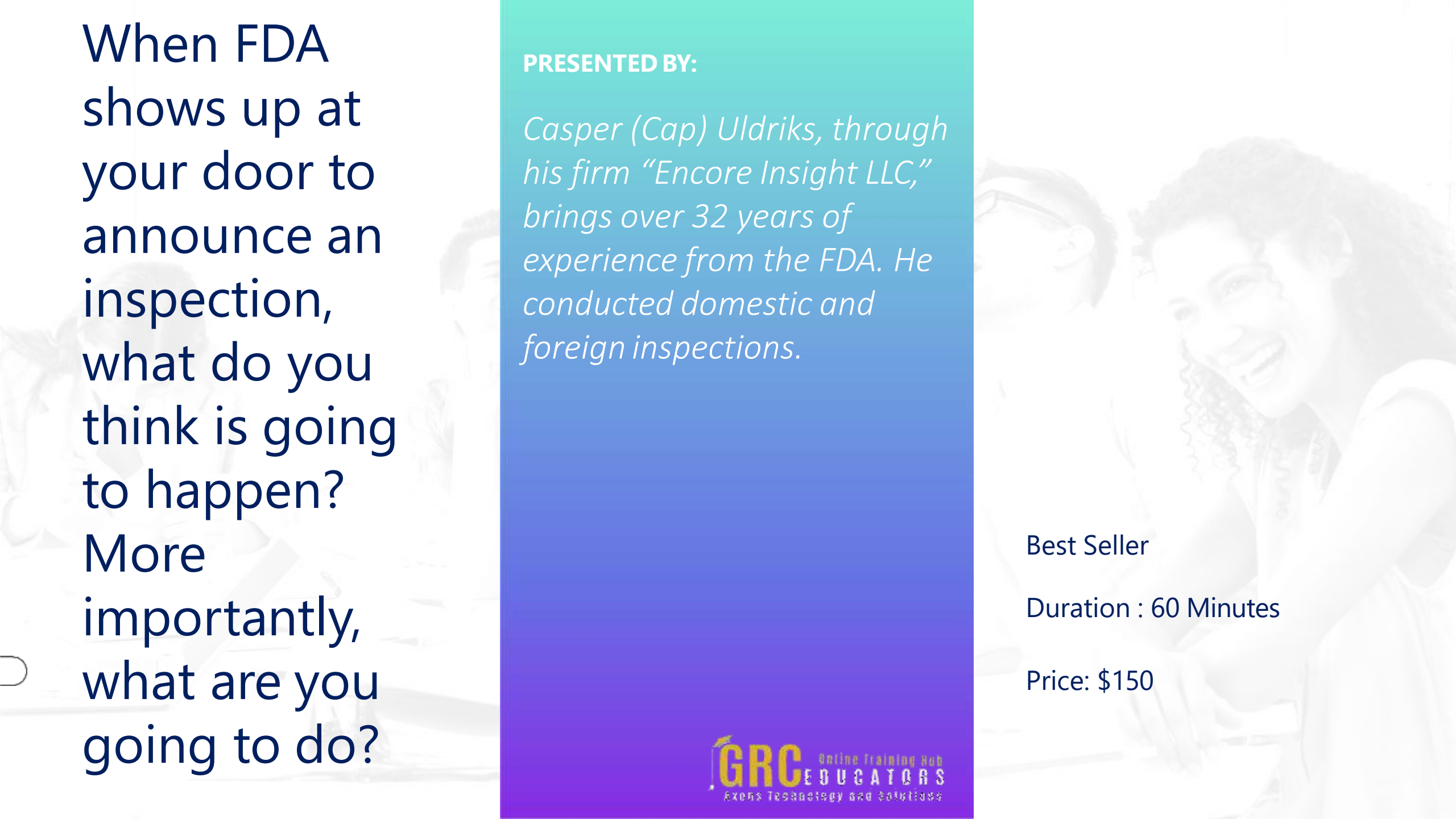


Best Seller

Duration : 60 Minutes

Price: $150

Webinar Description

When FDA shows up at your door to announce an inspection, what do you think is going to happen? More importantly, what are you going to do?

An ex-FDA investigator will conduct this webinar to share an "insider's" perspective about inspections. What's important, what's not, and what is a fatal mistake on the part of a firm. Firms need an established FDA inspection protocol that describes what happens during an inspection, what the roles are for employees and how to interact with the FDA.

How you manage an FDA inspection may have a tremendous impact on your firm's current and future regulatory posture with the FDA. A negative outcome can be costly in terms of money, lost business and onerous legal enforcement, such as seizures, injunctions, and prosecution. Prior knowledge about what happens during an inspection and how you can avoid deep pitfalls will serve you well and save you a lot of anxiety and in some cases your job.

FDA conducts inspections of food, drug and device manufacturers and sponsors of new products. Some inspections are announced, some are not. In either case, regulatory requirements may not be the biggest problem. It may be what you do or don't do or say during the inspection itself that puts you in jeopardy. Some firm's conduct alone puts them in hot water. There are behaviors and activities that likely need to be tuned up before the inspection stalls on an avoidable pitfall. Some pitfalls should be obvious, others are tricky, so you need to think before you speak or act.

Who Should Attend ?

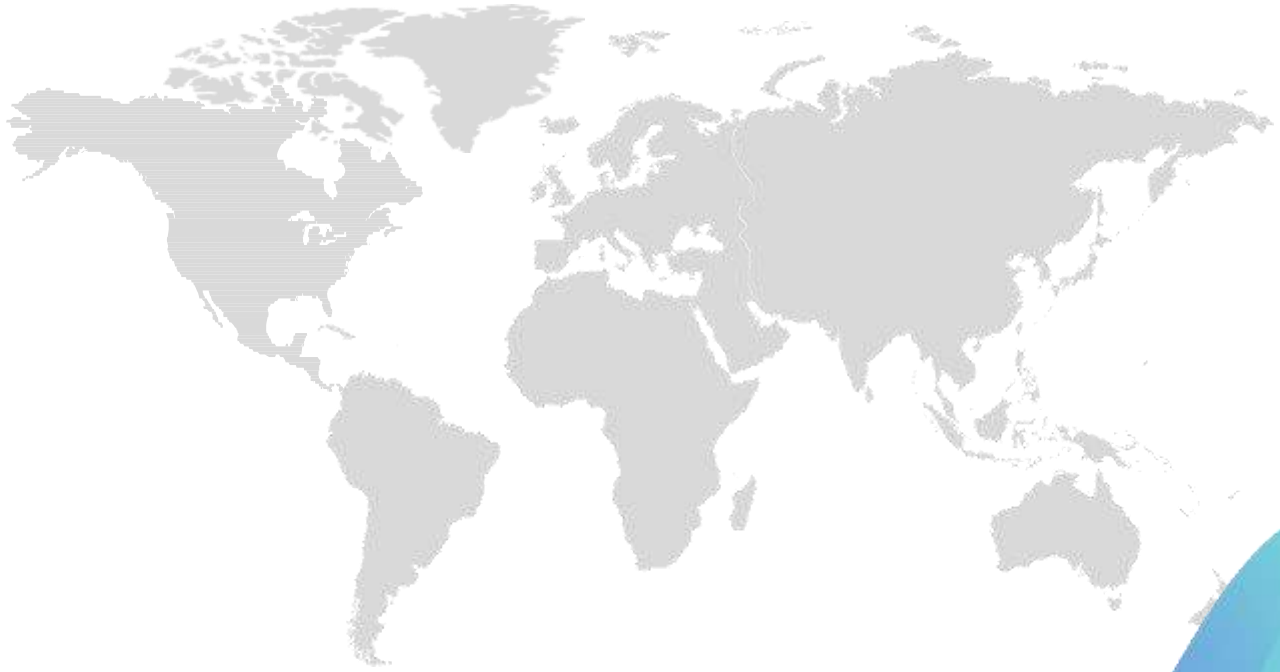
Regulatory Affairs Manager

Quality Assurance Manager

Manufacturing Managers

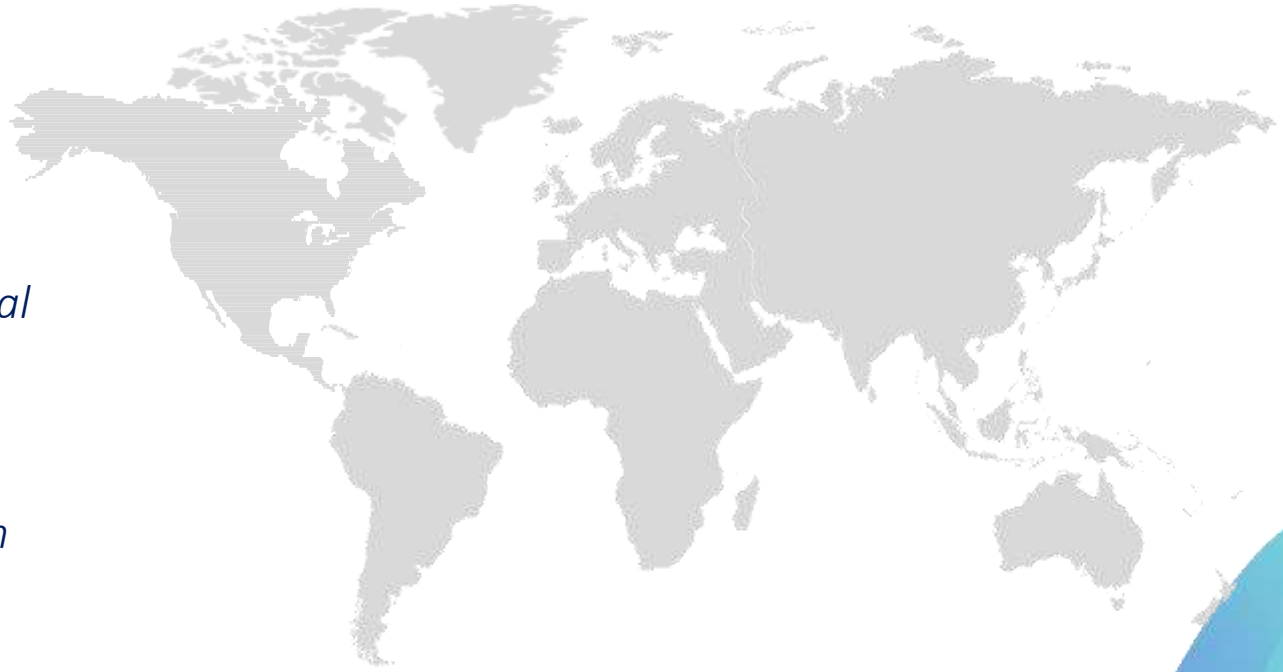
War Room Participants

Legal Counsel



Why Should Attend ?

The FDA investigator operates with an internal radar that sets off an alarm when you do or say something that is contrary FDA's inspection program and the statutory underpinnings of federal law. Undergoing an FDA inspection should not be like driving blind in the middle of a storm. The FDA "storm" is bad enough. Closing your eyes to the implicit dangers of how you manage an inspection is less than helpful to your firm.



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