GRC Online Training Hub
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Webinar on

How FDA Trains its Investigators to Review CAPA and What Should You do to Prepare

Date : August 20, 2021

Areas Covered

- *Documents Used by FDA Inspectors Operations Manual (IOM)*
  - *CAPA Implications, by Section*
    - *- Requirements*
    - *- Recommended Methods of*
    - *- Compliance for Each Requirement*

- *CPG Manual 7382.845*
  - *CAPA Implications, by Section*
    - *- Requirements*
    - *- Recommended Methods of Compliance for Each*
    - *- Requirement*

- *Compliance for Each Requirement*
  - *QSIT Manual*
    - *Description of each CAPA*
    - *Inspectional Objectives*
    - *Description/explanation*
    - *Recommended Methods of Compliance*

This session will discuss all the documents used by the FDA to train their inspectors to review your CAPA system.

PRESENTED BY:

Jeff Kasoff, RAC, CMQ/OE has more than 30 years of experience in Quality and Regulatory management. Over that time, Jeff has implemented and overseen quality system operations and assured compliance, at all sizes of company, from start-up to more than $100 million in revenue. This multi-faceted experience makes Jeff uniquely qualified to address compliance issues across the entire range of company sizes.

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Date : August 20, 2021

Time : 01 : 00 PM EST

Duration : 60 Minutes

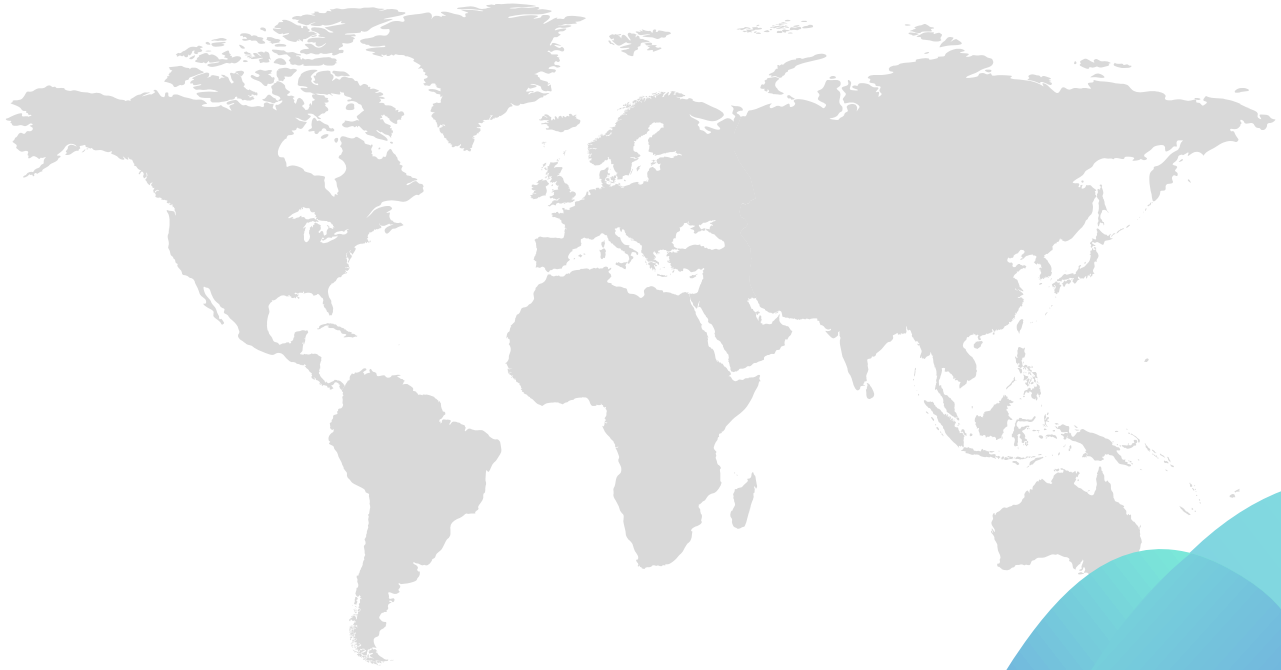
Price: $179

Webinar Description

During an inspection, FDA personnel will take a great deal of time reviewing your company's CAPA system. What will they look for? This session will discuss all the documents used by the FDA to train their inspectors to review your CAPA system, some of which you may not be familiar with. Also contained in this session will be a a section-by-section summary of the CAPA subsection of the QSIT, the document by which FDA inspectors operate during an inspection, as well as how your company can use that same document in your preparation.

Why Should You Attend ?

CAPA is the most cross-functional of all subsystems of your QMS. Firms have different CAPA processes which utilize different definitions and terminology for the same meanings. Having advanced knowledge and awareness of what to expect during the FDA inspection will drastically assist your firm in the ability to anticipate the inspector's questions, and how to "translate" your CAPA system into what the inspector is looking for.



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