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Webinar on

Management Controls Under QSR and ISO 13485

Date : July 23, 2021

Areas Covered

- *QSR and ISO 13485 requirements for management controls*
- *Organizational structure*
- *Establishment of an internal audit program*
- *Establishment of your company's quality policy*
- *Quality plan vs. Quality objectives*
- *Management reviews: Getting the most bang for your buck*

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This webinar will provide valuable assistance to all companies who have ISO certification or are registered with FDA.

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 : July 23, 2021

Time : 01: 00 PM EST

Duration : 60 Minutes

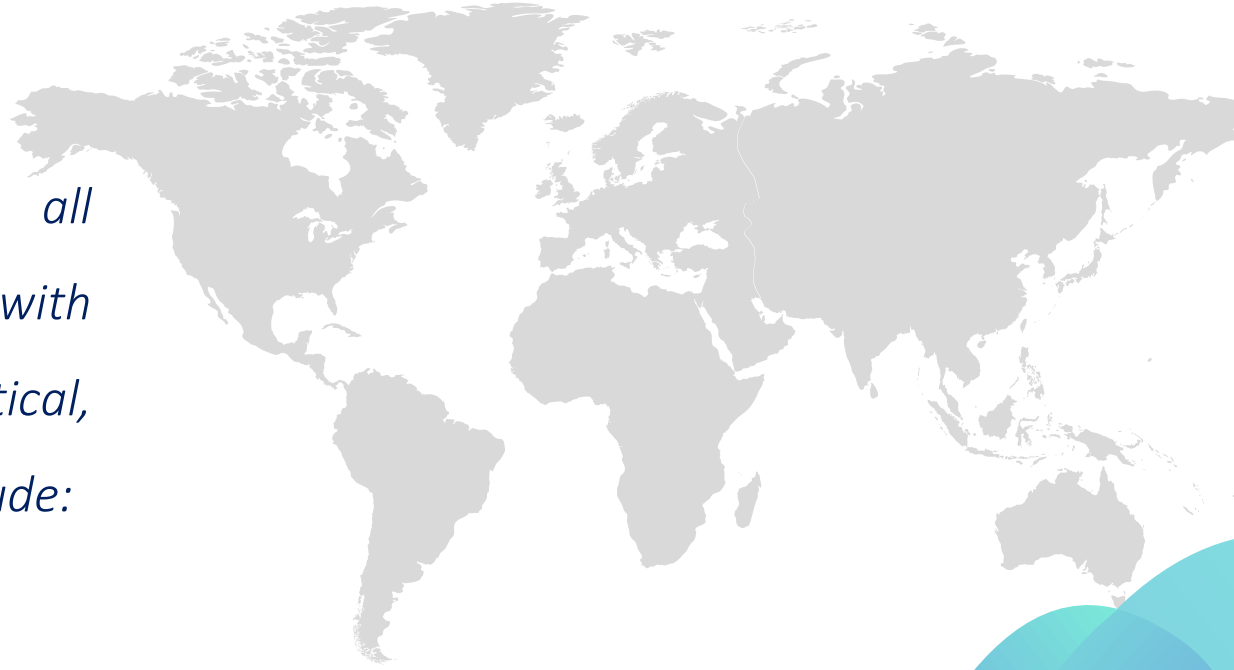
Price: $179

Webinar Description

The top management of a company is responsible for ensuring that all regulatory requirements are met.

This concept is codified in both the QSR and ISO 13485. FDA officials have repeatedly stated that the management controls subsystem is the central subsystem because it is the "glue that holds the quality system together." Since it is individuals in top management that the FDA will typically seek to fine or prosecute in the event of major non-compliance, this session is key for those individuals who are members of the top management, or those regulatory professionals who need to understand these requirements to assure top management are fulfilling its responsibilities. This session will discuss the requirements for Management Controls, including organizational structure, internal audits, the establishment of a quality policy, and confirmation it is being followed, establishment and contents of a quality system and quality plan, and of course all aspects of management reviews.

Who Should Attend ?



This webinar will provide valuable assistance to all companies who have ISO certification or are registered with FDA, across the Medical Device, Diagnostic, Pharmaceutical, and Biologics fields. The employees who will benefit include:

- *Executive Management*
- *Regulatory Management*
- *Regulatory Affairs and Quality Assurance Professionals*
- *Consultants*
- *Sales/Marketing Management*
- *Senior and mid-level Management*
- *Quality System Auditors*

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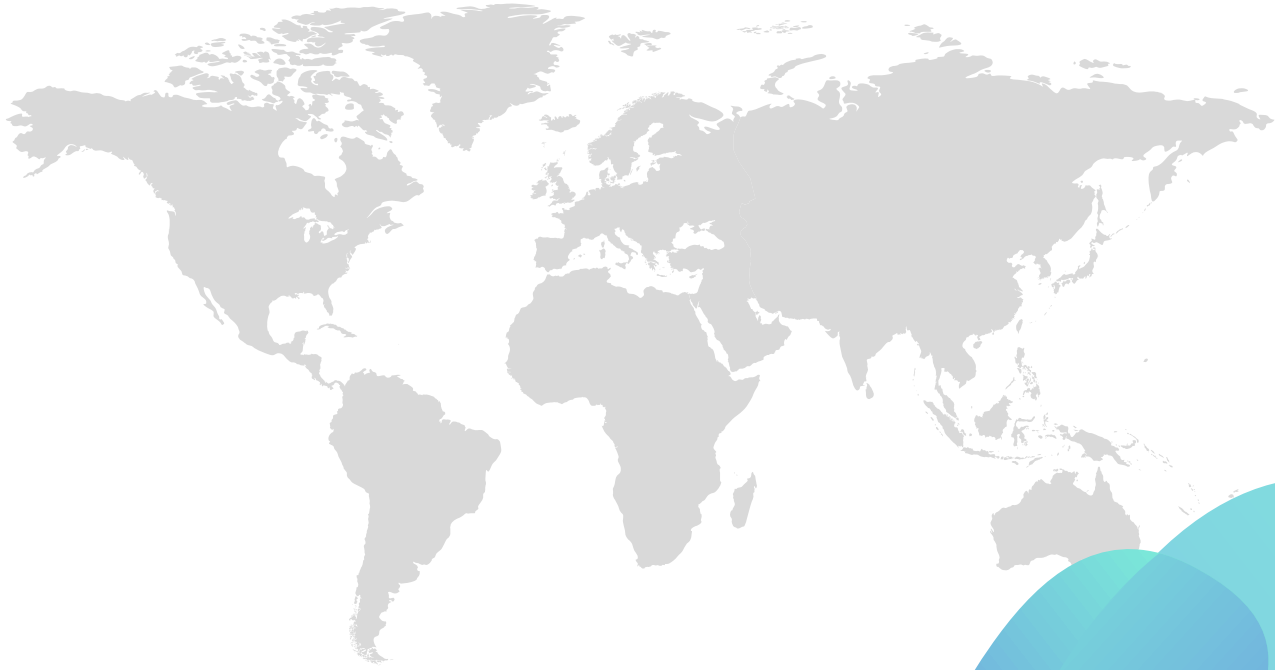
Why Should You Attend ?

The top management of a company is responsible for ensuring that all regulatory requirements are met. Top management must be directly involved in the QMS. This webinar will provide proven interpretive practices that have been determined to be in compliance with the regulations and hints on how to utilize management controls on a routine basis.

Management Controls is much more than merely management review. Many more systems must be in place to assure your firm is in compliance with the regulations.



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