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*Webinar on*

# Developing and Managing an Effective Change Control Program

# Learning Objectives

- *Regulatory Guidance Review*

  *FDA (CFR)*
  *EU (EurdraLex)*
  *ICH Q10*

- *Review all Elements of a Change Control Record*

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Regulatory agencies require pharmaceutical and medical device companies to have a systematic approach to managing all changes made to a facility, their product or a quality system.

**PRESENTED BY:**

*Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems; as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation.*

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On-Demand Webinar

Duration : 90 Minutes

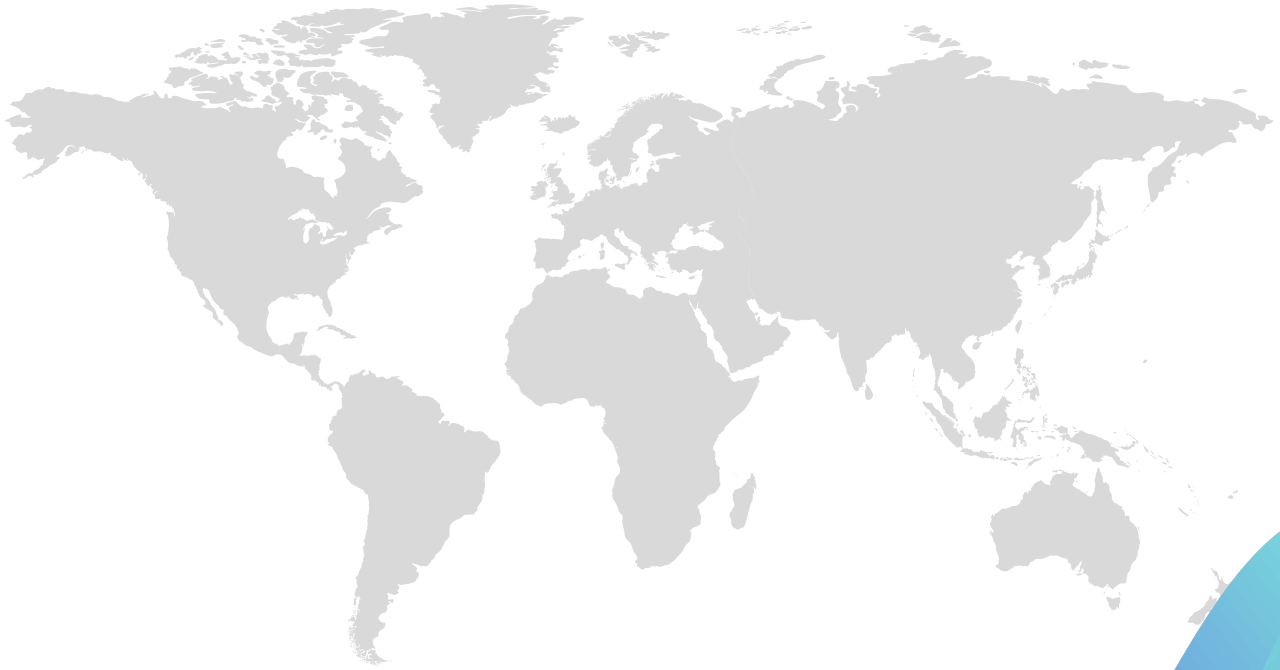
Price: $200

# Webinar Description

Regulatory agencies require pharmaceutical and medical device companies to have a systematic approach to managing all changes made to a facility, their product or a quality system. Given the fact that changes are inevitable, it is essential that companies have a compliant and effective change control program to ensure that no unnecessary or cGMP non-compliant changes occur. This Change Control training course will discuss regulatory expectations from the FDA, EU and ICH perspective, review all the required components of a thorough Change Control program; as well as, discuss the elements regarding successful management an effective Change Control system.

# Who Should Attend ?

*Operations employees that participate in Manufacturing, Engineering, Validation, Quality Assurance, and Regulatory Affairs as part of their job function – includes employees in the following departments:*



*Production*
*Engineering & Validation*
*Facilities / Maintenance*
*Quality Assurance*
*Regulatory Affairs*

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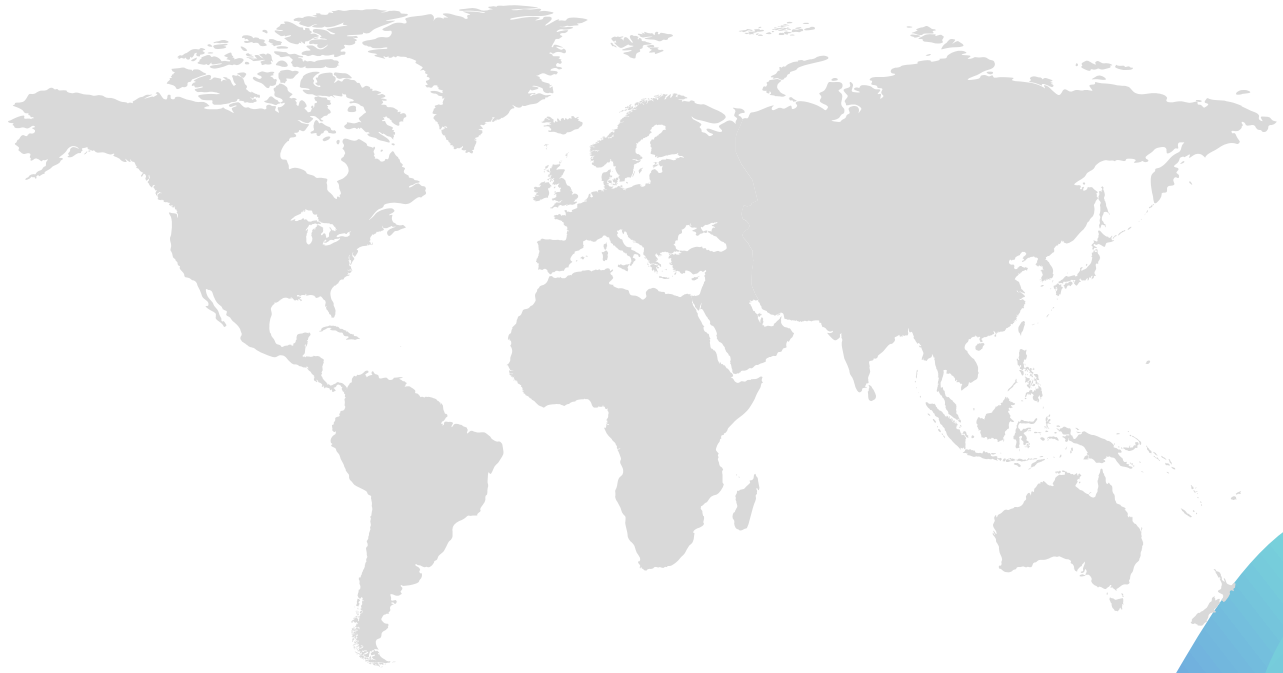
# Why Should Attend ?

- *Interpret the requirements of the FDA, EU and ICH guidelines regarding compliant Change Control records*
- *Understand all the required components of a thorough Change Control record*
- *Understand all the elements of effective Change Control management*
  - *How to develop a cross-functional team to ensure proper evaluation, approval and implementation of proposed changes*
  - *Ensure changes do not negatively impact the business or established marketing authorization*
  - *How to incorporate a Quality risk-based approach to evaluating proposed changes*
  - *Ensure changes are implemented in a timely manner by effective use of the Change Control Review Board (CCRB) and Quality Metrics*
  - *Understand what steps should be taken post-implementation to confirm the objectives were achieved*



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