

Webinar on

Sponsor's Responsibilities for an Active IND

Learning Objectives

Understanding each and every Sponsor responsibility in greater detail helps mitigate any delays in the clinical study or minimize the chances of a clinical hold

The webinar will help the sponsor, or the company understand the each of the processes (including the new protocol, Protocol revisions, new investigator) as well as the information amendments and its associated timelines for seamless conduct of the clinical study

Learning the IND safety reporting Regulations, follow up reporting and timelines

Insight into IND inactivation and withdrawal

This webinar will shed light on all the sponsor's responsibilities for an Active Investigational New Drug application (IND).

PRESENTED BY:

Gowri Sukumar is the Director, CMC and Regulatory Affairs for Iteration Therapeutics, Houston, TX. Unique to her experience is leading all the technical disciplines of CMC development as well as regulatory Affairs.

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

This webinar will shed light on all the sponsor's responsibilities for an Active Investigational New Drug application (IND). Alongside this presentation would detail each of the sponsor's activity in greater detail including timelines to implement the same. What's more; the discussion will also detail the safety reporting regulations and associated timelines.



Who Should Attend ?

Regulatory affairs professionals

Senior management executives (CEO, COO, CFO, etc)

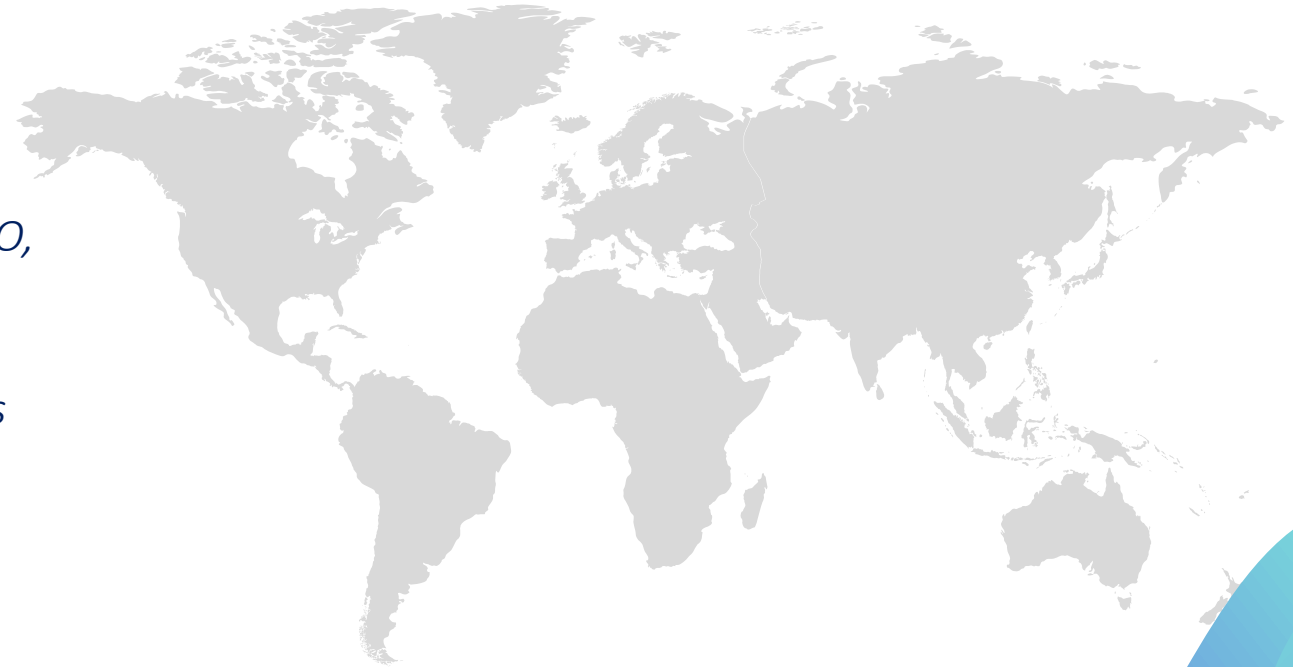
Drug discovery and development professionals (R&D and CMC)

Intellectual property experts

Project Managers and Clinical trial specialists

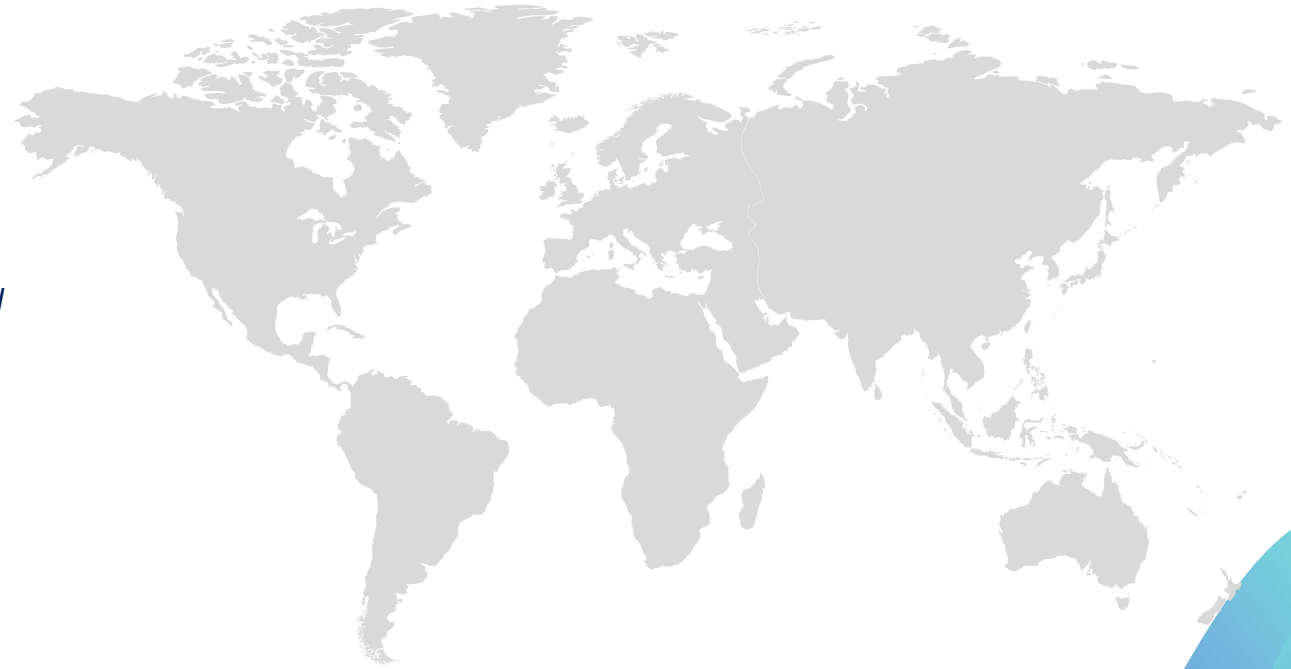
Regulatory Compliance Associates and Managers

People investing in FDA-regulated product development projects



Why Should Attend ?

It is important for the sponsor(s)/Pharma companies to understand every aspect of the Sponsor's obligation once an active IND is in place for a clinical study. Understanding the process and its associated timelines are critical in order for the sponsor to avoid or mitigate delays or risk of Clinical hold. Also critical is understanding the regulations around mandatory safety reporting.



To register please visit:

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