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Webinar on

Understanding Initial IND Submission - The First 30 Days

Learning Objectives

- *Understanding each step and the associated process(es)s in greater detail helps the sponsor to improve the chances of success to start the clinical study*
- *The webinar will help the sponsor, or the company understand the FDA's grounds on imposing clinical hold and also options for mitigating that risk*
- *In the event of a clinical hold; one can learn the options and ways to handle the same*
- *Tips on the best practices for the dialogue between the Sponsor and the FDA during the initial submission phase would also help the sponsor plan and organize the submission of the initial IND to minimize delays or potential hold*

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Areas Covered

- *Overview of the basic steps to the process for the initial 30 days after an initial IND is submitted to the FDA*
- *Understanding each step and the associated process(es)s in greater detail*
- *Definition and types of a clinical hold, Rational for imposing a clinical Trail hold for phase I by the FDA*
- *Identification and options for resolution of the clinical hold, Analyzing the options for the sponsor's response to a clinical hold, Understanding the differences in status between hold, inactive & Terminated*
- *Some tips on the best practices for the dialogue between the Sponsor and the FDA during the initial submission phase*

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This webinar will shed light on the entire process that takes place from the time the sponsor submits the initial IND to the FDA for initial 30-days.

PRESENTED BY:

Gowri Sukumar is the Director, CMC and Regulatory Affairs for Iterion Therapeutics, Houston, TX. Unique to her experience is leading all the technical disciplines of CMC development as well as regulatory Affairs. She has broad responsibilities that include process development, Drug Substance and Drug Product manufacturing from the CMC side.

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On-Demand Webinar

Duration : 60 Minutes

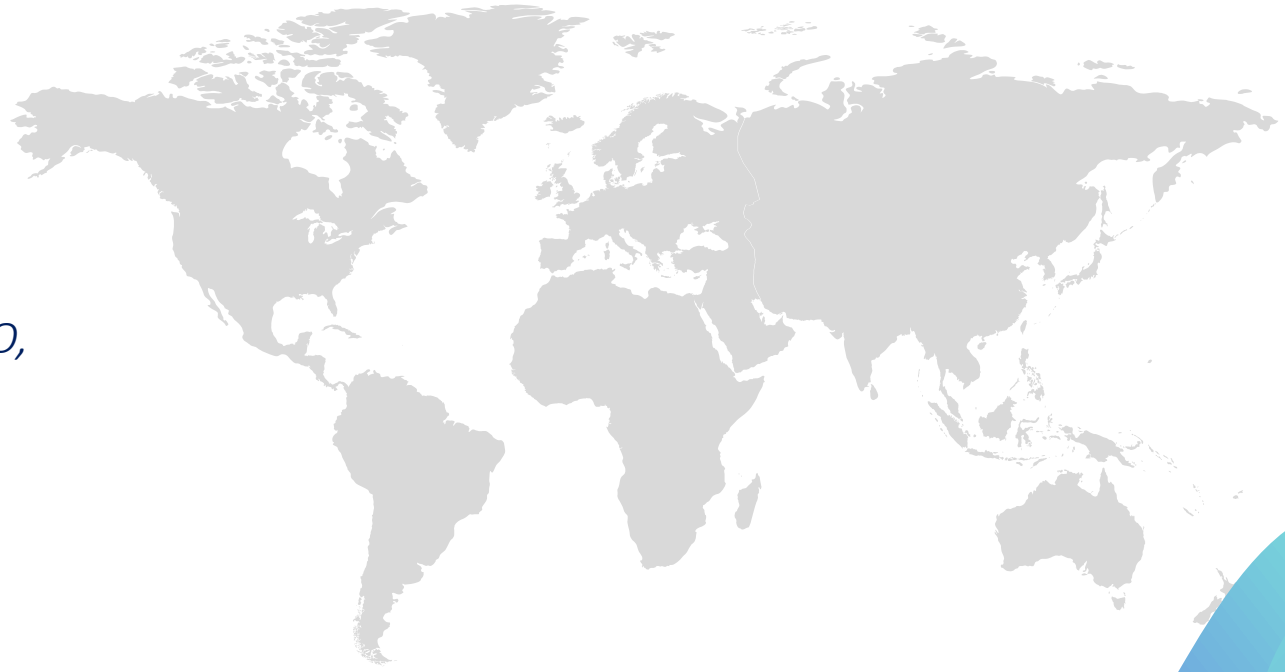
Price: $200

Webinar Description

This webinar will shed light on the entire process that takes place from the time the sponsor submits the initial IND to the FDA for initial 30-days. Alongside this presentation would detail the various grounds on which the FDA may consider placing a clinical hold. What's more; the options/ ways to respond to the clinical hold is also discussed to help the sponsor effectively work toward the resolution on the clinical hold.

Who Should Attend ?

The following professionals or disciplines will benefit from attending this Webinar:



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

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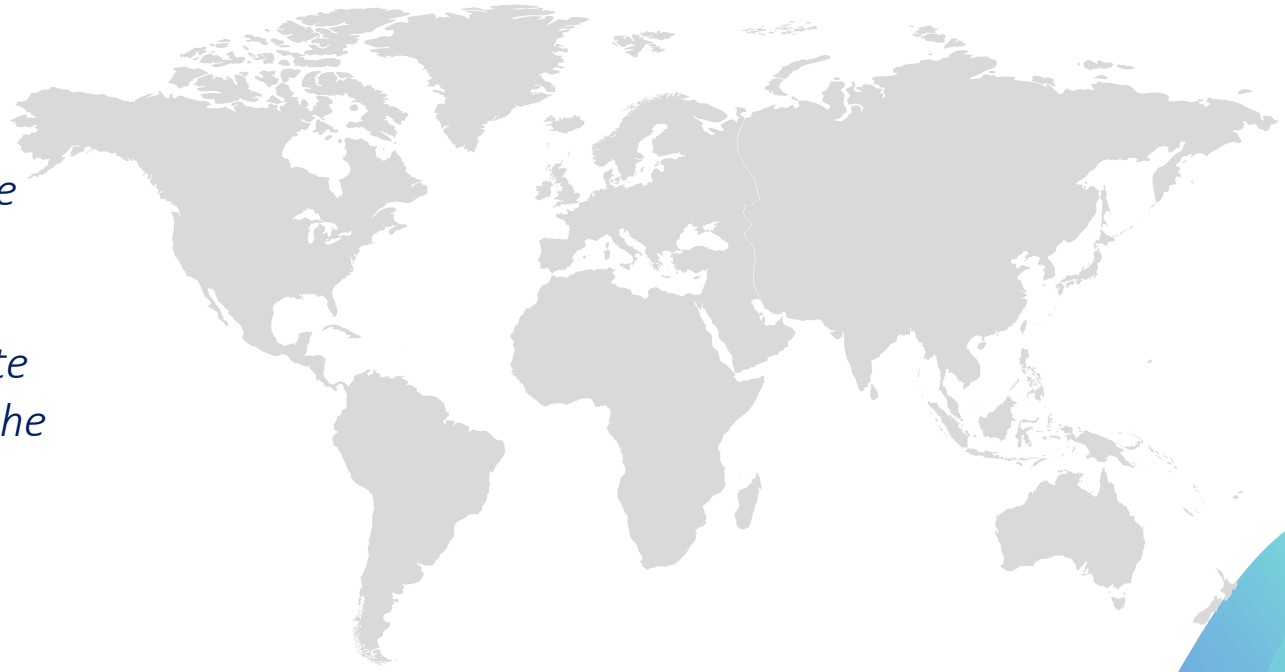
Why Should You Attend ?

It is important for the sponsor(s)/ Pharma companies understand the process/ steps once the initial IND is submitted to the FDA. Understanding the rational for imposing the clinical trial hold is critical in order for the sponsor to avoid or mitigate this risk. Clinical hold not only delays the start of the clinical trial but also adds to the capital and other resources utilized for the clinical study.



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