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Webinar on

Review Of Chemistry, Manufacturing And Controls (CMC) Of An Investigational New Drug Application (IND)

Learning Objectives

- *Outline of the relevance of information from the CMC perspective*
- *Understanding differences between small molecules and Biologics*
- *The glimpse of CFR 312.22 with the highlight of the FDA's primary objectives in reviewing an IND*
- *Overview of Pre-IND activities*
- *CMC package: IND content and Format with emphasis on the Drug Substance and Drug Product*

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This webinar will cover the key aspects of CMC package. .

PRESENTED BY:

Gowri Sukumar is an Associate Director, CMC and Regulatory Affairs for ESSA Pharmaceuticals. 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

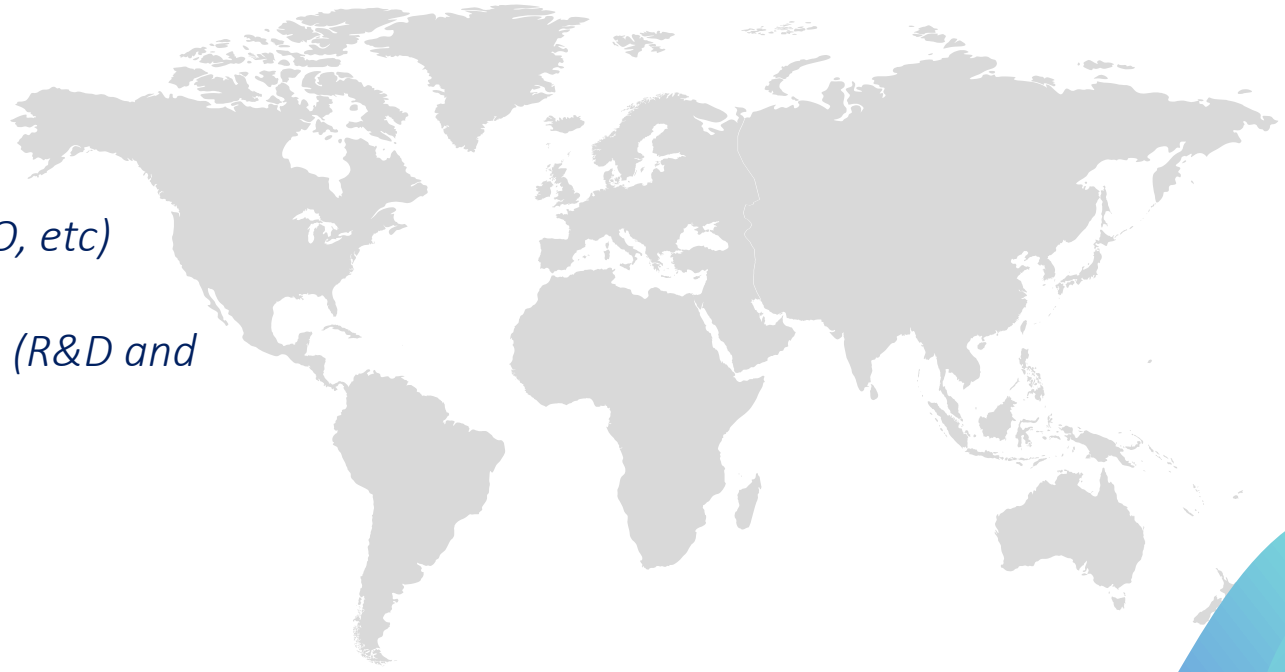
Duration : 90 Minutes

Price: $200

Webinar Description

This webinar is designed to help pharma companies through the various key aspects of the Chemistry Manufacturing and Controls (CMC) information expected by FDA in an IND (Investigational New Drug) Application. The presentation will cover the key aspects of CMC package. And will explore the individual requirements across both the Drug Substance as well as the Drug Product sections of the CMC package.

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

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