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Webinar on

FDA's GMP Expectations For Phase I & First-IN-Man Clinical Trials

Learning Objectives

- *Gms for IND products*
- *GMPs for Combination Products and 505(b)(2) Products*
- *Process Validation for Early and late Stage GMP*
- *Outsourcing Early Stage Outsource Manufacturing*

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This Webinar will provide details on GMP requirements throughout all phases of development and commercializati on.

PRESENTED BY:

Peggy J. Berry, MBA, RAC, is the President & CEO at Synergy Consulting where she provides consulting services to companies in all aspects of drug development. She also provides group and one-on-one training in drug development, regulatory affairs and project management topics. She is the editor of the 2010 book "Choosing the Right Regulatory Career" (RAPS, MD) and author of the 2011 book "Communication & Negotiation" (RAPS, MD).

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

This Webinar will provide details on GMP requirements throughout all phases of development and commercialization.

Following Good Manufacturing Practices (GMPs) is a mandatory legal requirement from clinical studies through-out marketing. Early clinical trials are conducted to establish the initial safety of a drug. The studies are generally in a small number of healthy subjects and use lower doses of the drug product. Therefore, only small amounts of investigational material are required. In order to not undertake substantial costs and to reduce regulatory burden during these early stages, the FDA has established guidelines to allow early stage investigational products to be manufactured under less stringent GMPs

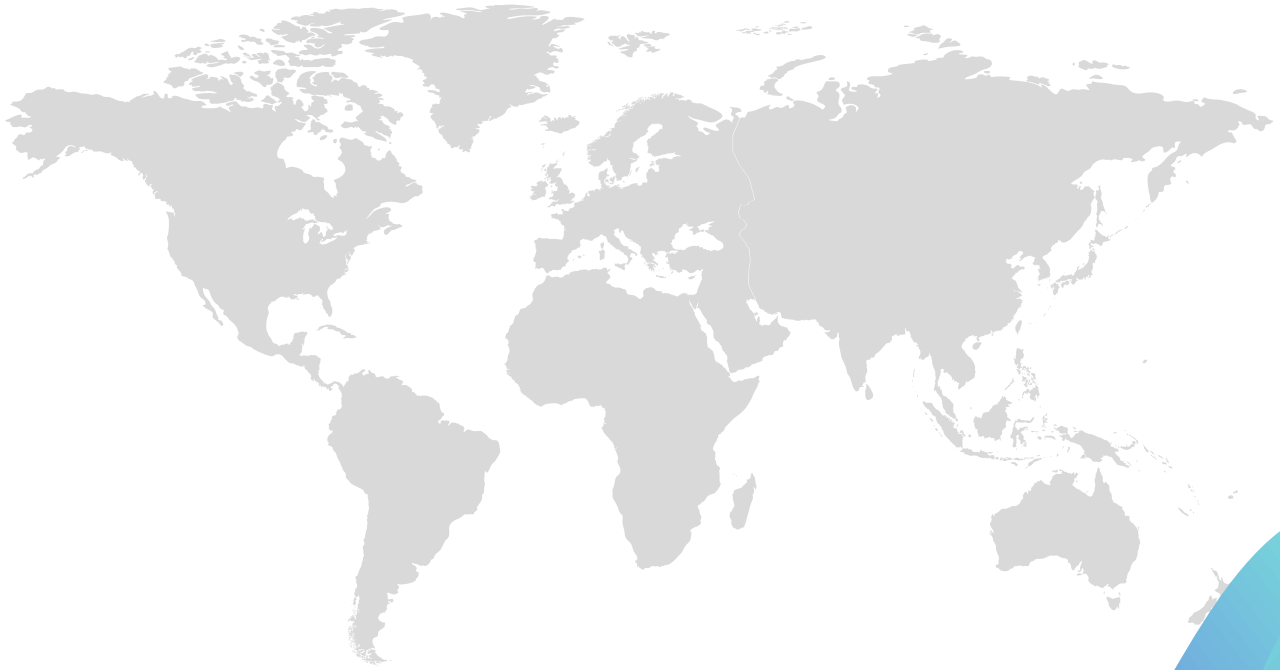
Who Should Attend ?

Directors

Manager

Supervisors

Lead workers in Regulatory affairs Quality Assurance and Quality Control



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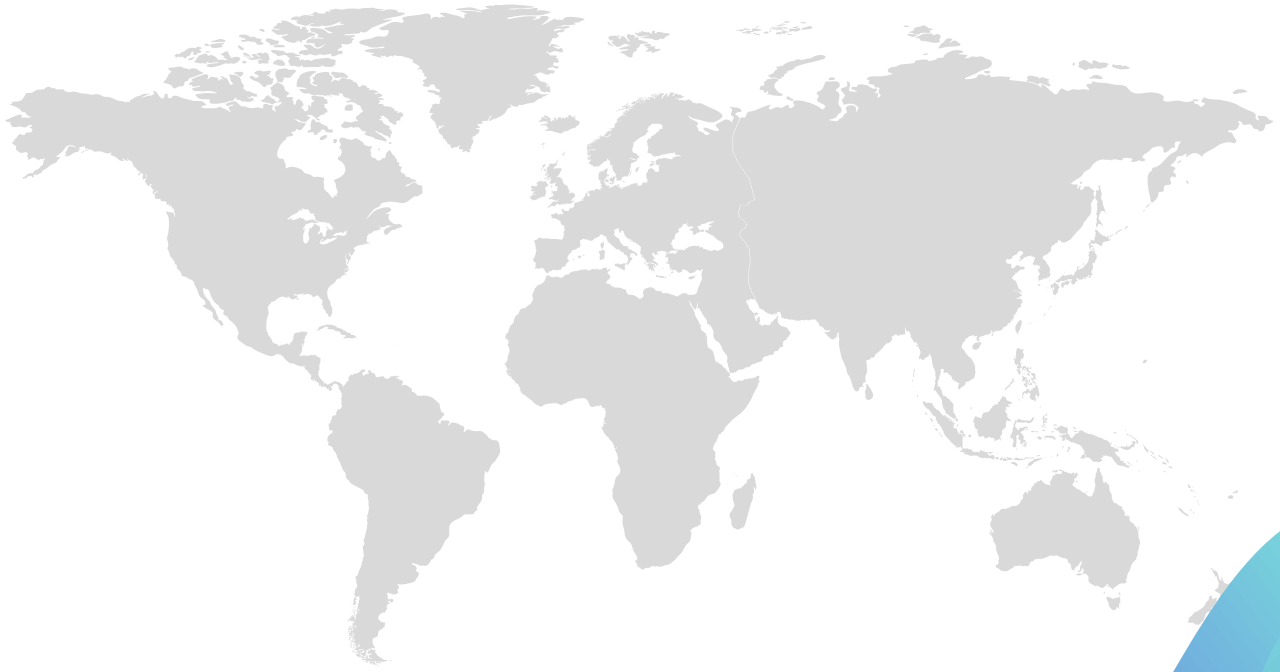
Why Should Attend ?

Attend this conference so that you may understand differences between GMP requirements for early and later stage clinical development. Explore and discuss ways to develop and implement strategies for early GMPs for phase I clinical studies.



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