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Webinar on

FDA Meeting Requests , Preparation And Conduct

Learning Objectives

- *Standard FDA meeting types and timing*
- *General qualifying requirements, Preparing the briefing document*
- *Preparing the meeting request, Preparation for non-typical meetings*
- *Rehearsing for the meeting, Conduct of the meeting*
- *Post-meeting follow up, Non-typical FDA Meetings*
- *Documenting informal meetings and Correspondence*
- *Reference to meetings during future submissions*

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This session will provide you with the information you need to request, prepare for and conduct meetings with the FDA to maximize successful outcomes and receive actionable direction and information.

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. Prior to founding Synergy Consulting, she was Vice President of Regulatory Affairs at Insmed where she was responsible for the development and implementation of global regulatory strategies and the management and oversight of the regulatory affairs department.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

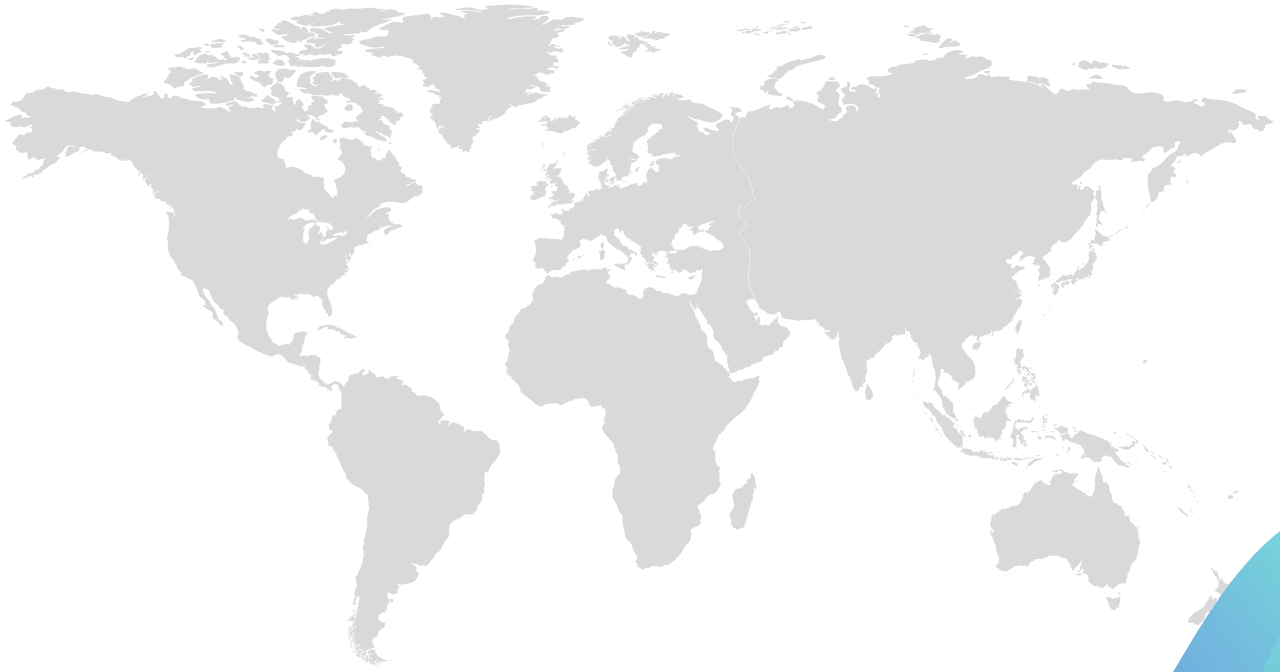
Webinar Description

The FDA has published guidance regarding the types of meetings that will generally be granted and the information needed to conduct the meeting. However, the guidance tends to be general and interpreted in multiple ways. This topic will provide practical examples and suggestions for standard meetings as well as requesting and conducting non-typical meetings (such as during fast track, the clinical hold, or for breakthrough therapy topics).

Rehearsal, post-meeting follow-up, and documenting nonformal FDA interactions will also be discussed in detail.

Who Should Attend ?

Regulatory affairs, Program management, project management, all personnel who may contribute to or participate in an FDA meeting.



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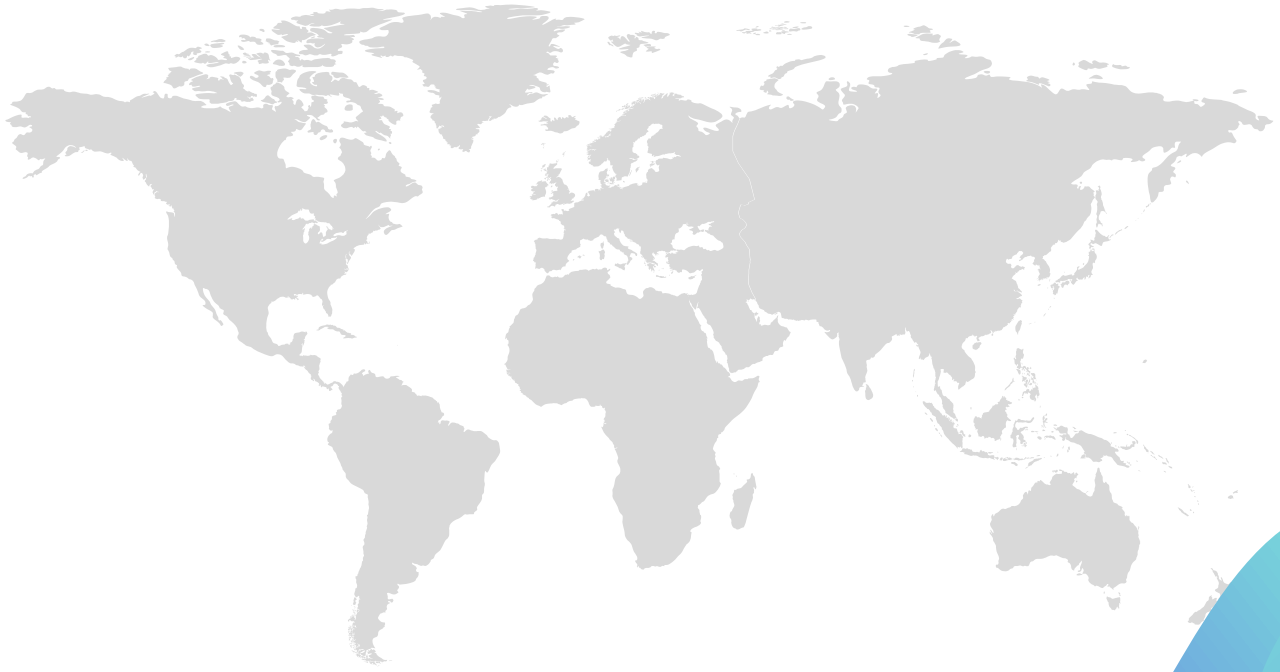
Why Should Attend ?

Obtaining feedback from the FDA at various times during the development process is crucial to the company to ensure that resources are not wasted and alignment is achieved. This session will provide you with the information you need to request, prepare for and conduct meetings with the FDA to maximize successful outcomes and receive actionable direction and information.



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