UPCOMING WEBINAR

SCENDEA

OHSU

Navigating FDA Interactions for Early-Stage Biotechs: A Guide to Successful Regulatory Engagements

Gain invaluable insights into the FDA interaction process for early-stage biotechs developing therapeutic or medicinal products.

This webinar will cover crucial topics such as when to approach the FDA, available meeting types, expected responses, data package requirements for an FDA IND request, and the significance of a well-crafted regulatory strategy.

WHEN

6th December
11:00 (PT)

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TOPICS

Scendea will cover...

The importance of having a plan & Regulatory Strategy

- Review an example drug development pathway and explore the critical role of a well-defined regulatory strategy in optimizing product development and achieving regulatory success.

When should I approach the FDA?

- Learn the optimal timing for initiating interactions with the FDA to ensure a streamlined regulatory process.

What are the options (meeting types) the FDA offer?

- Gain an overview of the various meeting types offered by the FDA and their respective purposes, helping you choose the most appropriate approach for your specific needs.

What response should I expect from the FDA?

- Understand the range of feedback and responses you may receive from the FDA, allowing you to effectively navigate the regulatory landscape.

Data package requirments when preparing/submitting an FDA IND Request

- Delve into the essential components of a comprehensive data package for an FDA IND request, ensuring compliance and expediting the regulatory process.

What are typical flags identified for programs in early development?

- Identifying typical flags raised during due diligence/gap analysis activities for programs in early development.
- Followed by a live Q&A Session with the Scendea speakers.

Key Learnings

Webinar attendees will leave with a deeper understanding of FDA interactions, equipped with the knowledge needed to navigate the regulatory landscape and enhance the likelihood of a successful product development journey.

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