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Webinar on

How Successfully Apply For A Breakthrough Therapy Designation

Learning Objectives

- *How to identify the characteristics for eligibility of a BTD product and determine whether your organization has such new drug products in their portfolio*
- *The proper format, content, and structure of the BTD application to ensure you will meet all of the requirements and provide FDA with an easy-to-review document that is very well written*
- *The BTD process and when it is the best time and opportunity to submit your application; doing this too early or late will create issues that can be easily avoided*

- *The significance of getting your product on a track for BTD designation, especially in terms of the pros and cons, costs, benefits, and compliance issues*
- *The process for resubmission, should your BTD application be denied/rejected to make the appeal go more smoothly*
- *How, as an organization, you should communicate your BTD status to the public in order to maximize the benefit to your bottom line and reputation*
- *What the best practices are and potential pitfalls and how to avoid them in order to make your submission one that will have the highest chance of approval while keeping down cost and ensuring compliance*

In this webinar, the applicants can request special meetings with FDA to discuss the development steps and become eligible for priority review.

PRESENTED BY:

Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, animal health, tobacco, e-cigarette/e-liquid and other FDA-regulated industries. She developed validation programs and strategies and collaborated with FDA and other industry representatives on 21 CFR Part 11, the FDA's electronic record/electronic signature regulation.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

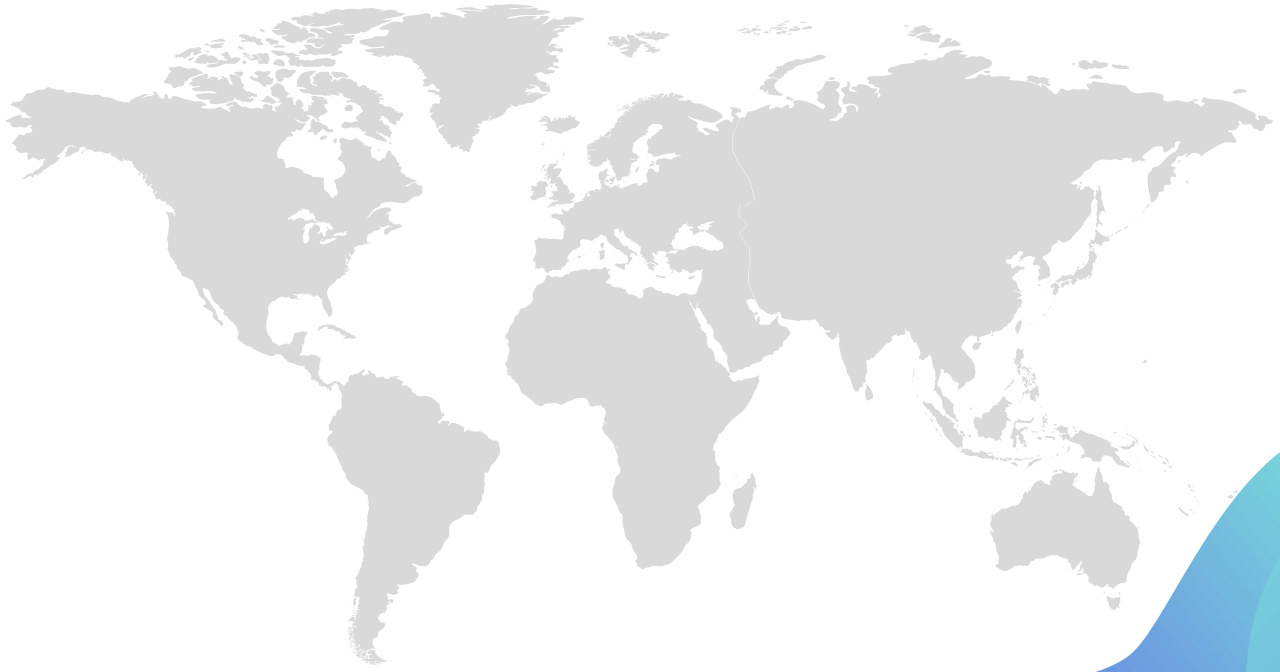
Webinar Description

The Breakthrough Therapy Designation (BTD) is perhaps one of the most impactful incentives from the FDA as it helps get the product to market much faster than any other expedited approval pathway. Once a drug is successful in getting the BTD, the non-clinical and clinical requirements for market approval are significantly reduced. The applicants can request special meetings with FDA to discuss the development steps and become eligible for priority review. However, getting a BTD is not easy; there is about 70% rejection rate for applicants of BTD; the success of BTD award depends a lot on the disease targeted and the product being developed, and BTD request requires significant resources from the applicant.

The Breakthrough Therapy Designation (BTD) process implemented by the US FDA facilitates expedited regulatory review of a drug candidate intended to treat a serious or life-threatening condition. To be designated BTD, the sponsor must share preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The program has been largely popular with the pharmaceutical/biotech industry since its introduction in July 2012 with the Food and Drug Administration Safety and Innovation Act (FDASIA) approval. By the end of March 31, 2016, the Center for Drug Evaluation and Research (CDER) had received 342 BTD requests (BTDR) of which 111 were designated BTD. Getting a BTD designation is hugely beneficial to the sponsor and according to some estimates can result in approximately 3.5 years less development time than a drug not granted any of the other expedited statuses by the FDA.

Who Should Attend ?

This web presentation is intended for those professionals that require knowledge about FDA's New Breakthrough Designation Program and the Other FDA Expedited Programs.



Regulatory Affairs Personnel
Manufacturing Personnel
Auditors
Clinical Research Associates (Monitors)
Legal Personnel
Lead CRAs
CRA Managers
Project and/or Study Managers
Project and/or Clinical Trial Assistants
Clinical Operations Administrators
Quality Assurance Personnel
Sponsor and CRO personnel
Auditors engaged in the internal inspection of clinical trial documentation and practices

Consultants working in the life science, tobacco and related industries who are involved in computer system implementation, validation and compliance would also benefit.

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