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Webinar on

Pre-Submission/Q-Sub for Medical Devices

Learning Objectives

- *Understand the USA FDA Pre-submission process*
- *Understand the types of Pre-Subs*
- *Understand the various types of FDA meetings*
- *Understand the logistics of an in-person FDA meeting*
- *Pre-Sub for a 510(k)*
- *Pre-Sub for a PMA*
- *Pre-Sub for an IVD*

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This webinar will discuss all aspects of the US FDA Pre-Submission process.

PRESENTED BY:

Grace Powers is an independent regulatory affairs consultant. She founded Powers Regulatory Consulting in 2015 to help clients with regulatory strategies and submissions. Her clients have included universities, investors, start-ups and mid-size medical device companies.

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On-Demand Webinar

Duration : 60 Minutes

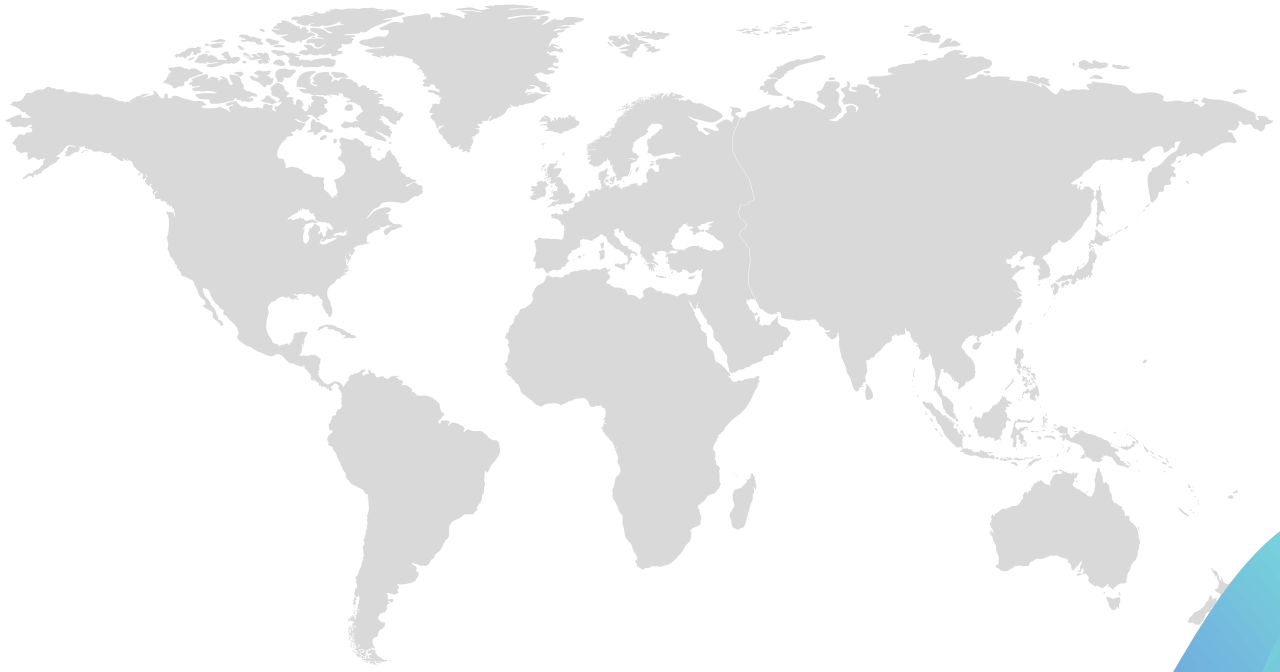
Price: $200

Webinar Description

This webinar will discuss all aspects of the US FDA Pre-Submission process. This webinar will review when a Pre-submission may be appropriate for a company or product. It will include a review of the guidance document. The types of Pre-submissions will also be reviewed including those for IDE applications, study risk determinations, Pre-Sub for a 510(k), Pre-Sub for a PMA and Pre-Sub for an IVD. The content needs for the various Pre-Sub types will also be explored. Questions that are appropriate for FDA Pre-Submissions will be discussed in great detail including examples of good and not so good questions for FDA. The e-copy required for Pre-Submissions will be reviewed as well as tips of the logistics of in-person meetings at FDA. Overall the webinar will include all the background needed to submit a Pre-Submission.

US Food and Drug Administration Pre-Submission (Q-Subs)

Who Should Attend ?



Inventors
Innovators
CEOs
CMOs
VPs
Compliance Officers
Regulatory Affairs - all levels
Clinical Affairs - all levels
Quality Assurance - all levels
Quality Engineering - all levels
Medical Scientists
R&D - all levels
Consultants
Contractors/Subcontractors
Anyone interested in the FDA Pre-submission proc

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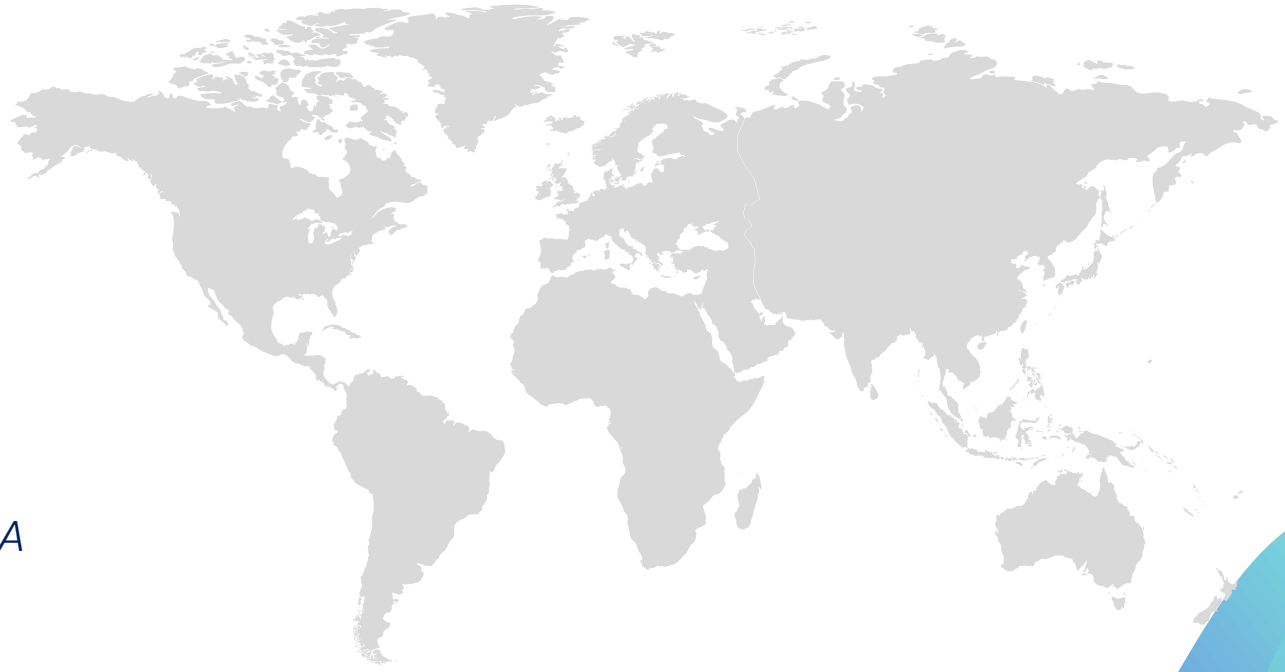
Why Should Attend ?



Attendees will learn the following:

What is a Pre-Submission?

When is a Pre-Submission appropriate for my company or product?

What types of questions are right to ask for FDA Pre-Submissions

Complete Background and Preparation required to submit Pre-Submissions

How will I get my feedback?

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