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Webinar on

Preparing A FDA 510(K) Submission

Areas Covered

- *510(k) unique terminology*
- *Refuse To Accept policy*
- *what is a predicate device*
- *Selecting a predicate device (substantial equivalence)*
- *Here to find substantially equivalent predicate devices*
- *How to handle software*

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In this webiner We will explain what a 510(k), its types and the procedure to prepare the submission.

PRESENTED BY:

Edwin Waldbusser is a consultant retired from the industry after 20 years in management of the development of medical devices (5 patents). He has been consulting in the areas of design control, risk analysis, and software validation for the past 8 years. Mr. Waldbusser has a BS in Mechanical Engineering and an MBA. He is a Lloyds of London certified ISO 9000 Lead Auditor and a member of the Thomson Reuters Expert Witness network.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

We will explain what a 510(k) is and the procedure to prepare the submission. The several types of 510(k) will be explained. Each part of the submission will be explained. The very confusing concepts of predicate device and substantial equivalence will be discussed. How to find an acceptable predicate device will be taught. FDA places special emphasis on-device software. We will cover the requirements for software.

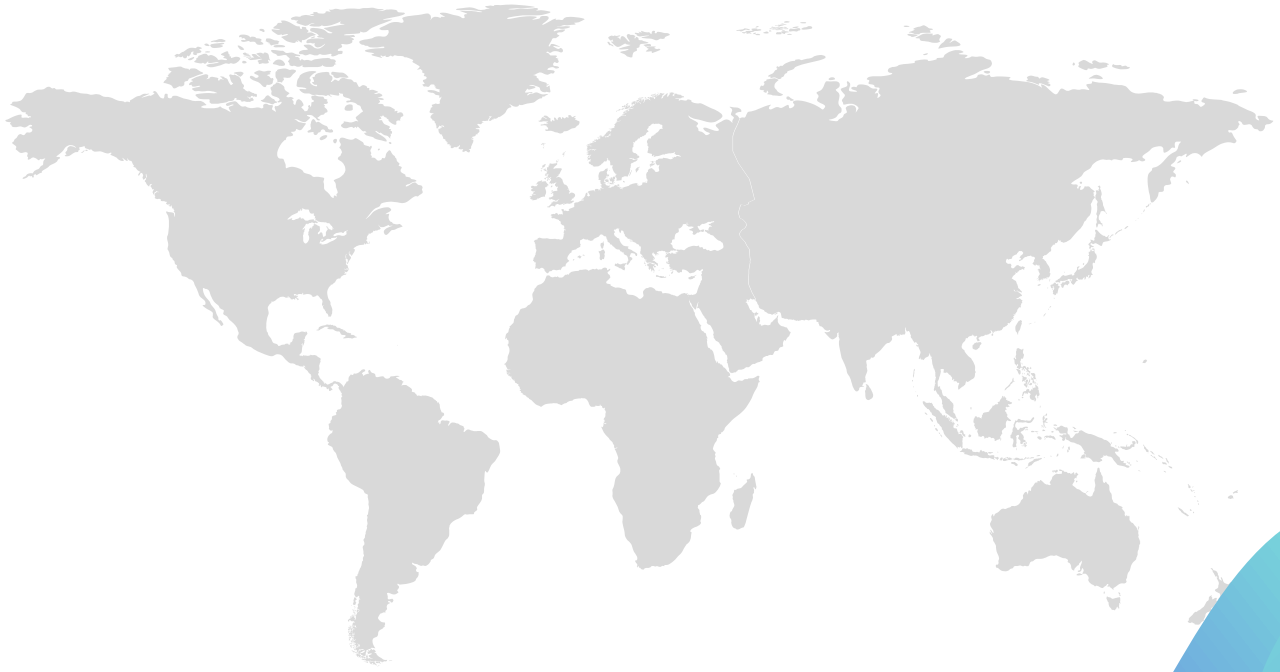
Who Should Attend ?

Engineering personnel

QA

software developers, IT

Management"



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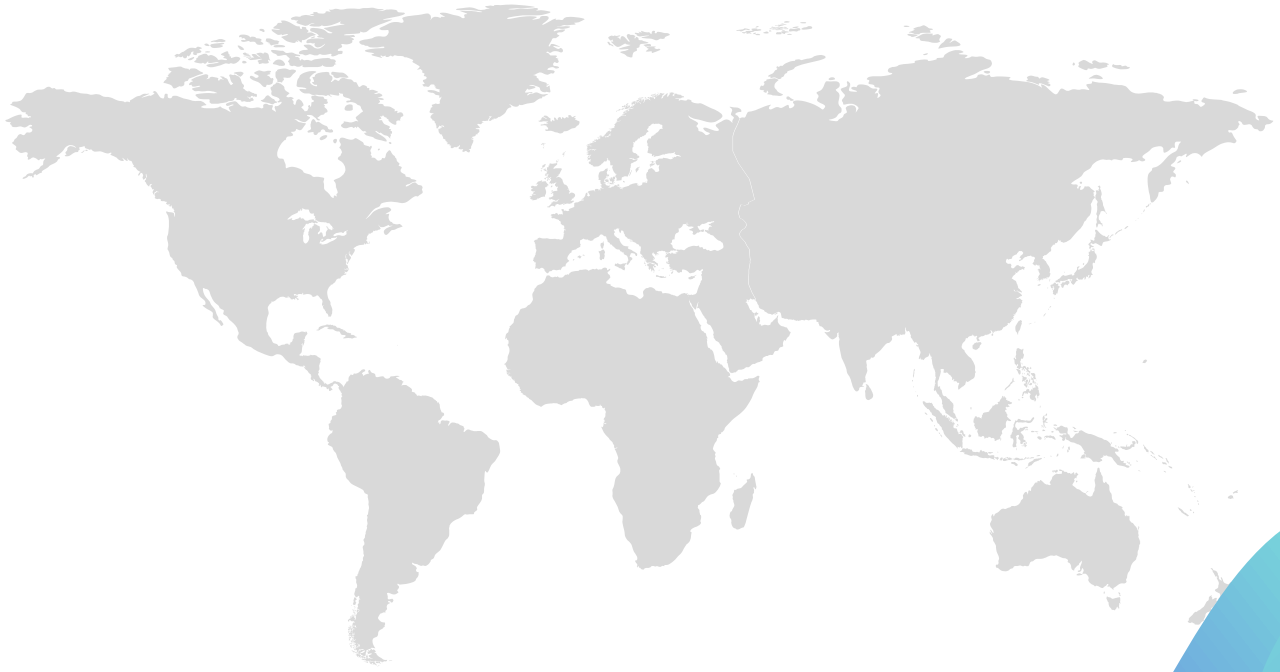
Why Should Attend ?

Preparing a submission to get FDA approval for a new product is time-consuming and confusing. The submission requirements refer to many unfamiliar concepts and terms. More than half of all submissions are rejected. We will teach you to prepare a submission meets all the FDA requirements.



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