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Webinar on

Analytical Method Validation For Pharmaceuticals

Date : 19 March 2019

Areas Covered

- *General Information*
- *Specificity*
- *Accuracy*
- *Precision*
- *Sensitivity*
- *Linearity*
- *Range*
- *Robustness*
- *Reproducibility*

This webinar discuss FDA Current Good Manufacturing Practice requirements include that validation of non-compendial analytical methods and the verification of compendial methods.

PRESENTED BY:

Dr. Loren Gelber has more than 40 years of experience in pharmaceutical industry regulatory compliance. She worked for about 10 years at the FDA, including as a reviewer in the Division of Generic Drugs. As an early user of HPLC, she was involved in establishing the FDA requirements for the validation of HPLC methods, and she published the results of her validations both within FDA and externally.

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Date : 19 March 2019

Time : 01 : 00 PM EST

Duration : 60 Minutes

Price: $179

Webinar Description

FDA Current Good Manufacturing Practice requirements include that validation of non-compendial analytical methods and the verification of compendial methods. The various aspects of validation or verification will be discussed, including the order in which they should be conducted and establishing specifications for success.

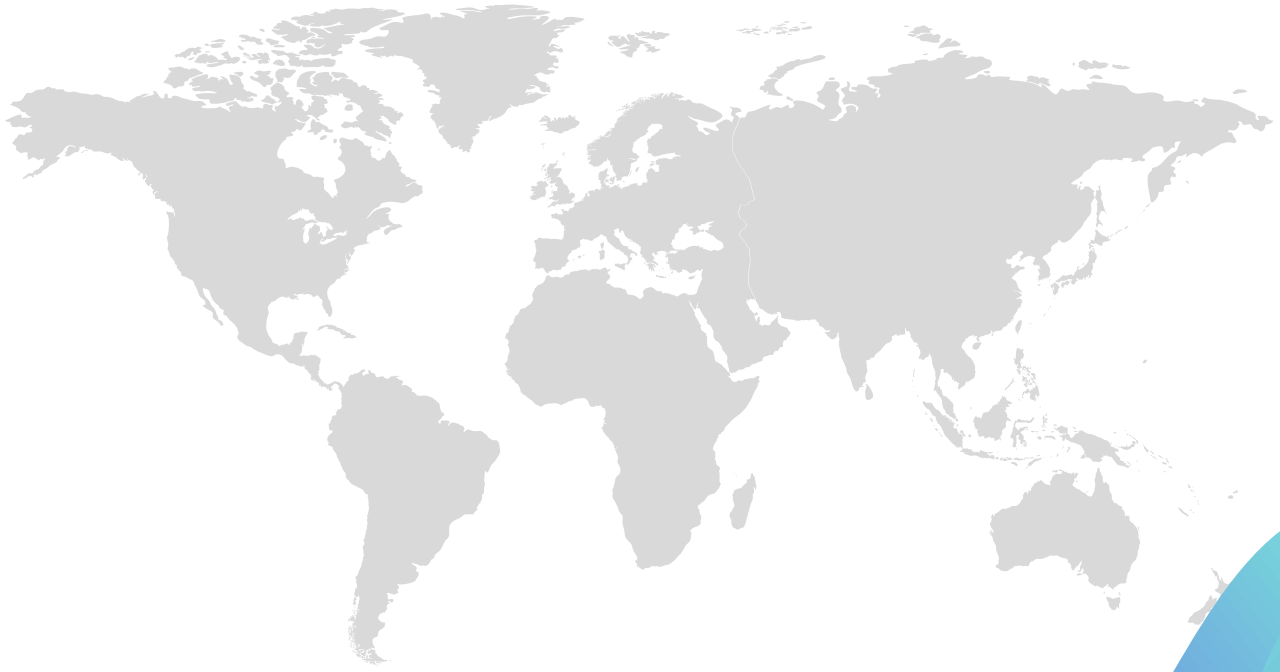
Who Should Attend ?

Analytical Chemists

QC and R&D Laboratory Supervisors

Regulatory Affairs

Quality



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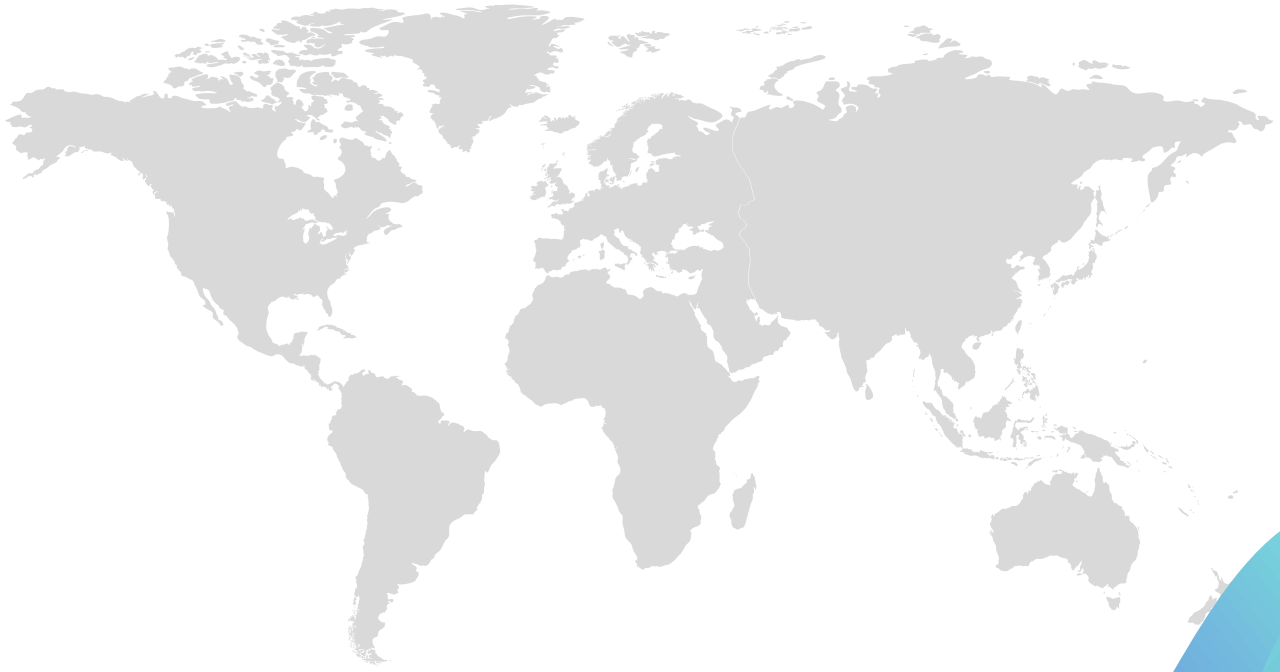
Why Should Attend ?

All chemists involved in the development and validation of analytical methods, those who supervise them and those who review or submit their method validation reports must know about the FDA rules for method validation. Defects or absence of validation or verification of analytical methods is frequent observations of FDA application reviewers and deficiencies during FDA inspections. Learning how to minimize these problems is highly recommended.



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