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Webinar on

Issues in Calibrations and Accuracy in Method Validation

Learning Objectives

- *GLP Regulations*
- *Quality Management System (QMS)*
  - *Definition*
  - *Principles, Purpose*
  - *Function, Elements*
- *Quality Policy, Quality Objectives*
- *Quality Manual, GLP SOPs*
- *Plan, Do Check, Act Cycle*
- *GAP Analysis*
- *QMS Implementation Steps*
- *Process Control and Optimization Theory*
- *Process Criteria,*
- *Quality Audit*
  - *Proposed Rule Summary*
  - *Cost of QMS*
  - *GLP QMS GAP Analysis Checklist*
  - *Sample GLP QMS Table of Contents*
  - *Example of Process Flow & Criteria*
  - *Required GLP SOPs*
  - *SOP Template*
  - *Seven Tools of Quality Management*
  - *Terms: Define & Differentiate*

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All of these changes create a very different system from the uppermost level of management downward in the organization chart.

PRESENTED BY:

John C. Fetzer has had over 30-years experience in laboratory compliance, including developing methods, writing SOPs, training, and auditing. He has served on the editorial advisory boards of the Journal of Chromatography, Analytical Chemistry, and Analytical and Bioanalytical Chemistry.

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On-Demand Webinar

Duration : 60 Minutes

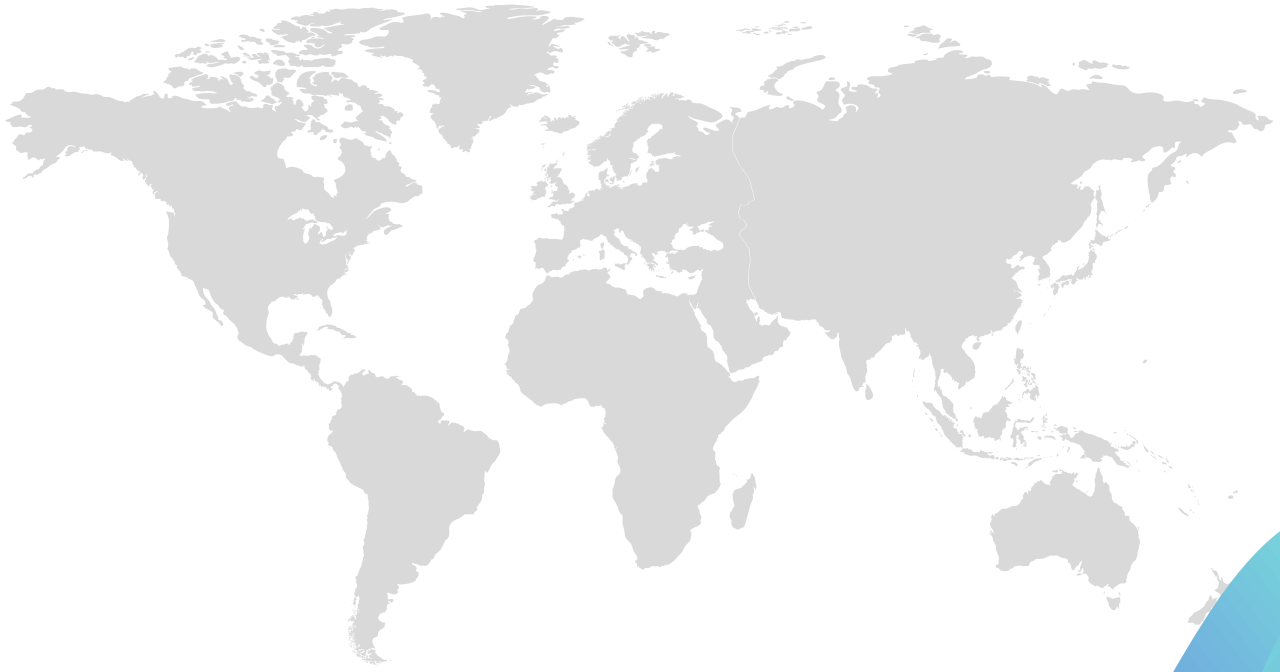
Price: $200

Webinar Description

The Quality Management System (QMS) is a set of policies and protocols for the acceptable operation of an organization that contains laboratories that must comply with US FDA GLP. Examples of roles and responsibilities, useful metrics, and tools to monitor performance, and useful documentation will be given.

Who Should Attend ?

Managers and supervisors of laboratory organizations



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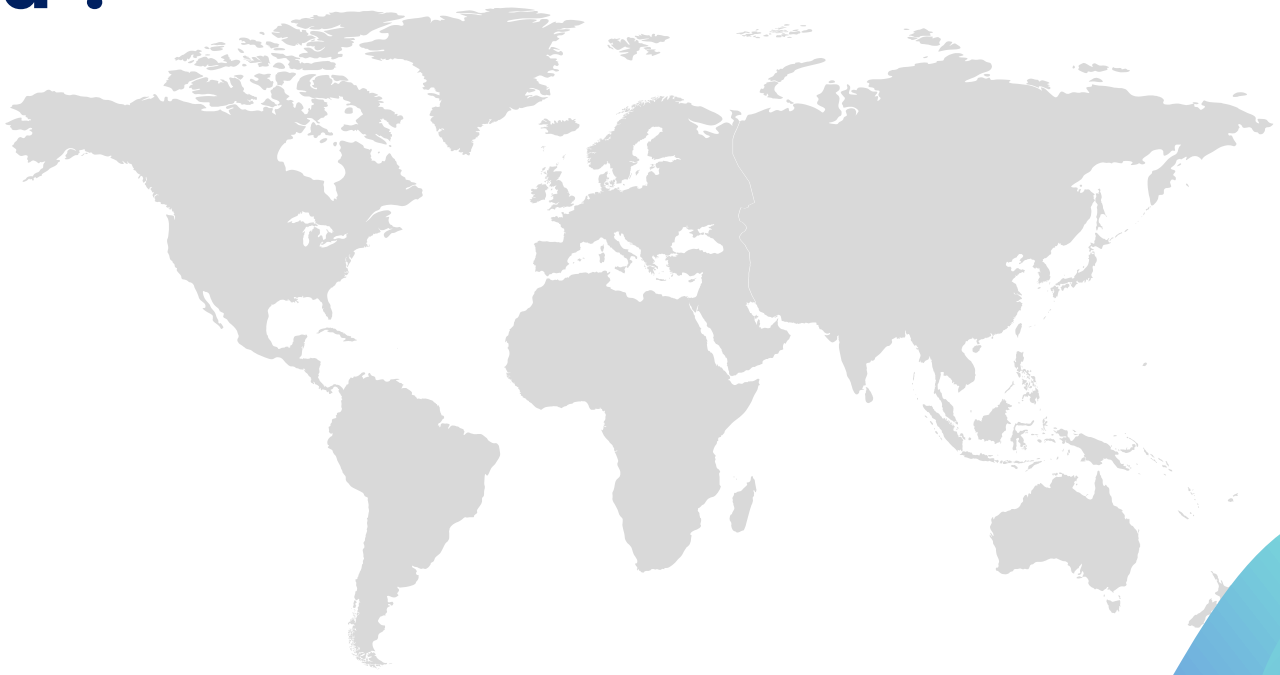
Why Should You Attend ?



In 2016, the US Food and Drug Administration proposed basic and wide-ranging changes to its Good Laboratory Practices. This has been published in the Federal Registry: Volume 81 Number 164. The roles of managers, supervisors, and staff are modified and assigned responsibilities are described. The requirements on organizations outside of the laboratory (facilities, sampling, purchasing, training, hiring, and so on) are made inclusive and required for compliance. Recordkeeping and documentation criteria and requirements are described. All of these changes create a very different system from the uppermost level of management downward in the organization chart.

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