



Audit Process and Readiness

Course description

In this course on the FDA audit process, participants will learn about the important procedures and guidelines involved in preparing for and successfully completing an FDA audit. The course will cover topics such as the difference between an audit and an inspection, the roles and responsibilities of the audit team members, and the types of questions and issues that may arise during the audit.

Participants will also gain an understanding of the FDA's expectations for compliance with regulations and guidelines, as well as the potential consequences of failing an FDA audit. They will learn about the best practices for maintaining compliance and avoiding common mistakes that could lead to audit failure.

At the end of the course you will able to:

- Define general inspection preparation activities.
- Define the Dos and Don'ts of an FDA inspection.
- Identify the team members of your audit team.
- Identify different types of questions during an FDA inspection.
- Understand the consequences of failing the FDA Inspection.
- Recognize the best practices of the industry for an FDA inspection.

Main topics

- 1 Inspections and Audits.
- 2 What is FDA?
- 3 FDA inspection purpose and scope.
- 4 What to expect from and FDA Inspection?
- 5 QSIT Inspection.
- 6 Audit Team: roles and responsibilities.
- 7 FDA Inspection Do's and Don'ts.
- 8 Consequences of failing the FDA Inspection.
- 9 Best practices of the Industry.

Contact

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Course features

Instructor Led 

Duration: 4 hours 

Tools and templates 

Simulated learning 

Course certification 