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# GMP Essentials for Management

## ***Purpose***

Leaders of the site must recognize the latest critical elements impacting the GMP compliance.

## **Objectives**

At the completion of the class, managers and executives will be able to:

1. State the top 10 reasons for receiving a 483 observation.
2. Explain FDA Inspections and the application of risk assessment.
3. Summarize GMPs for the 21<sup>st</sup> Century.
4. Explain risk assessment.
5. Explain Failure Mode and Affects Analysis.
6. Explain Quality by Design (QbD).
7. Explain Design of Experiments (DOE).
8. Describe the critical tools for conducting a root cause analysis.
9. Define the essential components and options of a deviation investigation report.
10. Explain the new approach to validation in light of risk assessment.
11. Explain the new direction of change control and regulatory filings.

## ***Prerequisite***

None

## ***Who should attend this course?***

This class is the GMP training you need if you are a manager, director, or vice president who is responsible for setting the direction for GMP operations at their plant site.

## ***About the class***

1. This class uses group-facilitated discussion, multi-media, problem solving activities and facilitated instruction to develop a solid understanding of CGMPs.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 16 hours.

**Topics Covered**

**Top 10 Reasons for Observations**

1. Annual observation chart
2. Case Study: Able Pharmaceutical

**Important Guidance Document Review**

1. GMPs for the 21<sup>st</sup> Century
2. Look for other guidance documents to be review

**Important Regulations for Review**

1. 21 CFR 1
2. 21 CFR 210

**Risk Assessment**

1. Defined
2. Uses
3. Planning FDA Inspections
4. Risk assessment and plant operations

**Failure Mode Effects Analysis**

1. Defined
2. Seriousness
3. Occurrence
4. Opportunity for detection
5. What to do with the data

**Quality by Design**

1. Defined
2. Elements

**Design of Experiments**

1. *Defined*
2. *Elements*

**Design Space**

**Current Tools and Practices in Deviation Investigations**

1. Goals of investigations
2. Possible outcomes

3. 5-Why's
4. Distinctions
  5. Walk through analysis
  6. Change analysis
  7. Control barrier analysis
  8. Fishbone diagrams
  9. Corrective action
  10. Preventive action
  11. Follow up

**Current Expectations on Deviation Investigation Reports**

1. Purpose of investigation reports
2. Problem statement
3. Previous investigations
4. Other affected materials
5. Root cause discussion
6. Root cause determination
7. Corrective actions
8. Preventive actions
9. Follow up

**Validation and Risk Assessment**

1. Validation and risk assessment
2. Design qualification
3. Commissioning
4. Installation qualification
5. Operation qualification
6. performance qualification
7. Process Control
8. Worst case
9. Edge of failure

**Change Control and Risk Assessment**

1. Defined
2. Change control and risk assessment
3. Supplier qualifications
4. HEPA Filters

5. Equipment use, cleaning and maintenance
6. Procedures and training
7. Levels of cleaning
8. Equipment cleaning logs
9. Work orders and repair orders
10. Log requirements and exceptions
11. Activity: Design A Dream Car

*Call to learn about how we can customize this outline for any of your site's GMP training needs!*