



cGMP TRAINING



Current Good Manufacturing Practices Overview for Management: Dietary Supplements

FDA 21 CFR Part III for Dietary Supplements

2 HOURS
Management
Overview



WHO SHOULD ATTEND

- Executives in the dietary supplement industry
- Non-technical audience
- Managers with no formal training in cGMP

PURPOSE OF THE WORKSHOP

- Provides a compact learning package that enables you to gain a working knowledge of cGMP
- Shows you how to apply cGMP principles
- Simplifies the regulations and helps you understand why you need to comply and what you need to do to comply
- Identifies regulatory expectations
- Shows you how to implement cGMP to avoid surprises in government audits
- Greatly reduces the risk of failing an audit
- Helps you prepare an action plan for implementing cGMP immediately on your return to the workplace
- Employs the interactive Mr. GMP Exercise™
- Answers your questions based on the most current interpretations of the cGMP regulations
- Gives you a participant binder, marked quiz, course certificate and The Green Book™, an indexed cGMP pocket booklet containing the CFR Part III Dietary Supplement Regulations. The Green Book™ will be an indispensable reference for your day-to-day activities in the workplace.

WORKSHOP OBJECTIVES

- Acquire and apply the basic concepts of cGMP
- Recognize the importance of cGMP compliance
- Understand the role of Quality Control

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cGMP Overview for Management: Dietary Supplements ...continued

FDA 21 CFR Part III for Dietary Supplements

WHAT YOU WILL LEARN

1. What is cGMP?

- a. Why is cGMP important?
- b. Basic expectations
- c. What is 21 CFR Part 111?
- d. FDA definitions
- e. What is CIPS?

2. cGMP for Dietary Supplements

- a. Personnel
- b. Facilities
- c. Equipment
- d. Production & process control
- e. Quality control
- f. Components & packaging
- g. Master manufacturing records
- h. Batch production records
- i. Laboratory

2. cGMP for Dietary Supplements (cont'd)

- j. Manufacturing, packaging & labeling operations
- k. Distributing
- l. Returns
- m. Products complaints
- n. Records

3. Good Documentation Practices

- a. Requirements
- b. Corrections
- c. Common documentation errors