



cGMP TRAINING



Fundamentals of Current Good Manufacturing Practices: Dietary Supplements

21 CFR Part 111 for Dietary Supplements

1-DAY
Interactive Training
Program



WHO SHOULD ATTEND

- Fabricators, packagers/labelers, testers in the dietary supplement industry
- New employees, those who have production experience with no formal training in cGMP
- Personnel with training who need to stay current with GMP

PURPOSE OF THE WORKSHOP

- Provides a compact learning package that enables you to gain a working knowledge of cGMP in one day
- Shows you how to apply cGMP principles
- Provides a methodical approach to cGMP that 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 or self-inspection
- Helps you prepare an action plan for implementing cGMP immediately on your return to the workplace
- Provides documented effectiveness of learning (completed quiz)
- Gives you plenty of practice so you'll leave with proven skills
- Employs interactive exercises (e.g., Mr. GMP Exercise™), industry based case studies, hands-on tasks designed to involve and engage the participant
- Emphasizes adult learning principles
- Answers your questions based on the most current interpretations of the cGMP regulations
- Gives you a participant binder, marked quiz, course certificate, indexed cGMP pocket booklet containing the CFR Part III Dietary Supplement Regulations, and Personal Action Plan™. The Blue Book™ will be an indispensable reference for your day-to-day activities in the workplace.

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cGMP TRAINING



Fundamentals of cGMP: Dietary Supplements ...continued

21 CFR Part 111 for Dietary Supplements

WORKSHOP OBJECTIVES

- Acquire and apply the basic concepts of cGMP
- Recognize the importance of cGMP compliance
- Apply the cGMP regulations to the Manufacturing and Distribution Cycle
- Understand the role of Quality Control
- Develop The Personal Action Plan™ to ensure compliance at your company

WHAT YOU WILL LEARN

1. What is cGMP?

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

2. GMP 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. GMP 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