

GMP Training Systems, Inc.

Creators of the GMP Ready-to-Use Training System™

Understanding cGMPs for Dietary Supplements

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

Learning Objectives

Upon completion of this workshop, participants will be able to:

- Understand FDA and cGMP terms they are likely to encounter.
- Understand the intent of the cGMP regulations.
- Have a thorough understanding of the breadth and scope of the cGMP regulations.
- Interpret sections of the cGMP regulation in order to apply them to real-world situations they are likely to encounter.
- Develop a personal commitment to comply with the GMP regulation.
- Recognize violations and potential violations of the GMP regulation.

Who should attend

This workshop is designed for anyone working in the dietary supplement industry whose job responsibility requires a comprehensive understanding of the basic concepts of current Good manufacturing Practice.

Workshop instructor

The instructor for this workshop is David Markovitz, President and Founder of GMP Training Systems, Inc. David's career includes nine years (1989 - 1998) where he headed all the education and training activities for Nutrilite Products, Inc., one of the pre-eminent manufacturers of dietary supplements. David knows this business.

Workshop outline

Our approach is hands-on and practical, not theoretical. We use proven adult learning techniques, which includes a diverse array of group discussion, lecture, video, demonstrations, and small group interactive activities.

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Day One - The Concept of Compliance

Day One consists of discussion around the specific topics listed below. cGMP is explored from a compliance viewpoint. Small group exercises are used throughout the session to enhance learning. Participants will engage in a cGMP audit using a videotaped scenario. Small group audit teams will then prepare a mock FDA-483 observation form and share their observations with the entire group. These small groups will then develop strategies to deal with each observation and more importantly, identify what could have been done to prevent the observation in the first place.

- Exploring the 8 P's of cGMP (Product, Process, Project, Paperwork, People, Patients, Position and Profit)
- How and why cGMP makes Good Business Sense
- The why behind the cGMP regulations. Exploring the intent of the regulations
- The history and evolution of Food and Drug law and the cGMP regulations
- The concept of operating in a "state of control"
- An inside look at the FDA and how they operate
- Interacting effectively with FDA - Dos and Don'ts
- Conducting a mock cGMP audit
- Identifying observations from the audit
- Developing recommendations to prevent audit observations

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Day Two - The Challenge of Performance

Day Two consists of discussion around the specific topics listed below. Whereas on Day One the emphasis is on cGMP from a Compliance viewpoint, this day focuses on cGMP from a business performance perspective. A Case Study approach is used to identify the specific requirements of each section of the cGMP regulation. Small groups are assigned certain sections of the regulations to examine in detail and prepare recommendations using the case study example.

- General Provisions
- Personnel
- Physical Plant and Grounds
- Equipment and Utensils
- Requirement to Establish a Production and Process Control System
- Production and Process Control System: Requirement for Quality Control
- Production and Process Control System: Requirements for Components, Packaging, and Labels for Product That You Receive for Packaging or Labeling as a Dietary Supplement
- Production and Process Control System: Requirements for the Master Manufacturing Record
- Production and Process Control System: Requirements for the Batch Production Record
- Production and Process Control System: Requirements for Laboratory Operations
- Production and Process Control System: Requirements for Manufacturing Operations
- Production and Process Control System: Requirements for Packaging and Labeling Operations
- Holding and Distribution
- Returned Dietary Supplements
- Product Complaints
- Records and Recordkeeping