

# Dietary Supplements GMP Compliance



## Quality & Compliance Essentials

***“I am responsible for Quality Assurance within a dietary supplement manufacturer, and I need a cost-effective way to provide cGMP awareness and 21 CFR Part 111 training to our entire workforce.”***

Regulatory bodies such as US FDA have regarded “dietary supplements” separately from pharmaceuticals, and generally categorized these products as “food.” The ingredients are predominantly made up of natural substances or substances derived from natural sources which in turn are assumed safe.

US FDA has been enforcing 21 CFR Part 111 cGMPs for Dietary Supplements since 2007. This regulation mirrors many concepts found in pharmaceutical Good Manufacturing Practices (cGMPs) and requires master manufacturing records, documented batch production records and testing of raw materials and finished products. Just as important, 21 CFR Part 111 indicates that the dietary supplement company is responsible for the product content as well as the product supply chain, from raw materials to finished product.

Our Quality & Compliance Essentials program, authored by the experts at Compliance-Insight, enables dietary supplement manufacturers to drive GMP awareness across all employees and contractors in a cost-effective but standardized manner.

This program includes six self-paced courses:

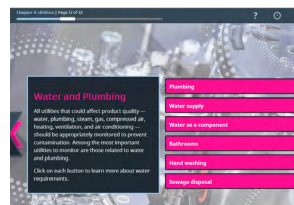
- cGMPs for Manufacturing Plants and Equipment
- cGMP Requirements for Quality Control
- Introduction to Part 111 cGMPs
- Packaging, Labeling, Holding and Distribution
- Production and Process Control System for Manufacturing Operations
- Requirements for Records and Recordkeeping **See reverse side for course details**



## cGMPs for Manufacturing Plants and Equipment

This course will explain FDA requirements for manufacturing plants and grounds including design and construction and requirements for sanitation, equipment and utensils, automated equipment, contamination prevention and recordkeeping.

### Dietary03



## An Engaging Learning Experience

To ensure the learners retain the material, each course contains “interactive quizzes” that must be completed before learners can move to the next chapter. Learners can take these quizzes as often as possible to achieve the 80% passing score. These attempts are not reflected in their qualification record.

In addition, courses contain a number of interactive buttons that learners must click before continuing to the next page. This idea of “chunking” information has been proven to improve retention in adult learners.

## Affordable Pricing

Pricing for the set is based on an organization’s employee size. For a firm with 500 employees, for example, the subscription cost works out to approximately \$20 per learner. These courses can be delivered in one of three methods:

- **SCORM:** Course files are provided in SCORM, so they can be delivered via your organization’s SCORM-compliant learning management system. Optional maintenance fees are available, in the event that the courses are updated to reflect new regulations.
- **AICC:** Course files are delivered as AICC, so they can be delivered via your organization’s AICC-compliant learning management system.
- **ComplianceWire®:** Courses can be delivered through UL’s ComplianceWire learning management system for an additional fee.

## cGMP Requirements for Quality Control

QC personnel are expected to ensure the quality of the dietary supplement a manufacturer makes as well as the correct packaging and labeling as specified in the master-manufacturing record. In this course, you will be able to identify regulatory requirements for quality control operations, including material review and dispositions, laboratory operations, product complaints, returned products and other process control operations.

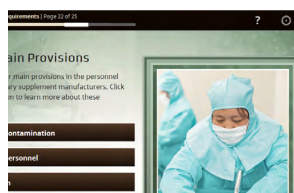
### Dietary05



## Introduction to Part 111 cGMPs

This course explains the origin and scope of cGMPs for dietary supplements. You will also be able to identify the purpose of general provisions and personnel subparts as well as the 16 basic subparts of the 21 CFR Part 111 Final Rules.

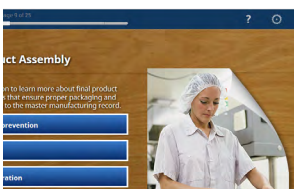
### Dietary02



## Packaging, Labeling, Holding and Distribution

This course is designed to help the learner become familiar with the requirements for dietary supplement product packaging, labeling, holding and distribution operations.

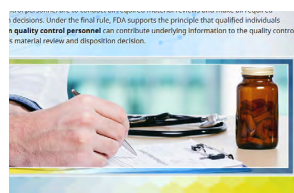
### Dietary01



## Production & Process Control for Manu. Operations

This course explains the cGMP process control requirements for manufacturing operations, including sanitation, contamination, rejected products, specifications, in-process adjustments, reserve sampling and records.

### Dietary04



## Requirements for Records and Recordkeeping

Just creating documents is not enough. You must follow specific established practices that allow everyone who reads your documentation to understand exactly what you mean. This course will help you recognize the importance of the master manufacturing record, batch production records, effective documentation practices, the requirements for records retention and Part 111 for electronic records.

### Dietary06



## Get Started

To learn more about the Dietary Supplement GMPs courses, or arrange a demo, please contact Pat Thunell at [pat.thunell@ul.com](mailto:pat.thunell@ul.com).