DIETARY SUPPLEMENTS:
GOOD MANUFACTURING PRACTICES
TRAINING COURSE

OBJECTIVES:

The objective of this course is to provide the trainees with a comprehensive understanding of the GMP minimum requirements for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement as described in FDA: 21 CFR Part 111 (final rule).

LEARNING OUTCOME

After completing this course, the participants should be knowledgeable with the GMPs necessary and minimum requirements to ensure the quality (purity and safety) of released product (the dietary supplement) for sale.

WHO WILL BENEFIT:

1. Regulatory/quality assurance personnel
2. Marketing personnel
3. Operational (production) managers
4. Middle-to-senior management

COURSE LENGTH:

One business day (seven hours).

INSTRUCORS:

Dr. Jalal Mokhalalati, B.Sc., M.Sc., Ph.D.

NOTE: Regulatory Authorities ask for the trainer credential to verify that the trainer is qualified to conduct the training.

HANDOUT MATERIALS

A binder, which contains the presentations' slides.

SOURCES AND GUIDELINES:

US Department of Health and Human Services; Food and Drug Administration, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements21 CFR Part 111, Final rule.

CONTENTS

SUBPART B: Personnel
SUBPART C: Physical plant and grounds
SUBPART D: Equipment and utensils
SUBPART E: Requirement to establish a production and process control system
SUBPART F: Requirements for quality control
SUBPART G: Requirements for components, packaging, and labels
SUBPART H: Requirements for the master manufacturing record
SUBPART I: Requirements for the batch production record
SUBPART J: Requirements for laboratory operations
SUBPART K: Requirements for manufacturing operations
SUBPART L: Requirements for packaging and labeling operations
SUBPART M: Holding and distributing
SUBPART N: Returned dietary supplements
SUBPART O: Product complaints
SUBPART P**:** Records and recordkeeping

COURSE PRICING

Please refer to the training page on our website for more details.

CERTIFICATIONS

Trainees who participate in this program will receive a "Certificate of Completion" from **QMRS.**

For more information, please contact:

Quality Medical Regulations Services (QMRS)
jalal@qmrs.com