GMPs AUDIT AND THE EXTERNAL INSPECTORS PRACTICES

COURSE OBJECTIVES

The objective of this course is to define the requirements, responsibilities, and procedures for Quality Assurance (QA) Compliance Audits and to describe the usual governmental inspection practices

LEARNING OUTCOME

After completing this course, the participants should be able to:

1. Define the requirements, and procedures for GMPs and Quality Assurance *Internal Audits*
2. Aware of the usual governmental inspector's practices and/or third party auditors.
3. Recommend specific methods and standards for responding to such inspectional activities
4. Ensure that periodic and planned audits of systems, training and documentation shall meet regulatory bodies and corporate requirements for current Good Manufacturing Practices,

WHO WILL BENEFIT

1. Quality assurance personnel/inspectors
2. Drug and Natural Health Products Operational (production) managers and middle-to-senior management
3. HACCP team members (coordinators)

CONTENTS

INTERNAL & SUPPLIERS AUDITS

Internal Audit

1. Scope, Criteria, planning, preparation, requirements , and techniques
2. Audit Observations Rating
3. The Audit Report
4. Audit follow-up

Suppliers Audits and Assessments

1. Authority, Scope, and Criteria
2. Site Audit Response
3. Audit Closeout

Clinical Research Organization (CRO) evaluation

Clinical Laboratory Evaluation

REGULATORY INSPECTIONS PRACTICES

Procedure

1. General (Basic Consideration)
2. Senior management participation
3. Types and scope of inspections
4. Regulatory actions

Role and authority of investigator

1. Evaluation
2. Record
3. Citation

Role of corporate management

1. Responsibility
2. Process management
3. Conduct and protocol

COURSE LENGTH

Two days

INSTRUCTOR

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

NOTE: Regulatory authorities usually ask for the trainer credential. To verify that the trainer is qualified to conduct the training, please click on My Credential

HANDOUT MATERIALS

A binder, which contains the presentations' slides

SOURCES AND GUIDELINES

1. ISO 9001:2000 Lead Auditor Course
2. ISO 9000:2000 Training
3. The auditor training program ISO 14001:2004
4. Canadian Food Inspection Agency (CFIA), Food Safety Enhancement Program (FSEP) Implementation Manual, Volume 2,

5. Drug Good Manufacturing Practices (GMPs) and Establishment Licensing (EL) Enforcement Directive (POL-0004)
6. Health Products and Food Branch Inspectorate: Good Manufacturing Practices Guidelines, 2002 Ed. Version 2

COURSE PRICING

Please click on the TRAINING section.

CERTIFICATIONS

Trainee who participate in this program will receive a “Certificate of Completion” from **QMRS**

For more information, please contact:
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