DRUG: GOOD MANUFACTURING PRACTICES TRAINING COURSE

Good Manufacturing Practices are measures designed to ensure an effective overall approach to product quality control and risk management by setting appropriate standards and practices for product, manufacturing, testing, storage, handling and distribution

OBJECTIVES
The objective of this course is to provide the trainees with a comprehensive understanding of the current GMPs requirements. Specifically,

1. Participants should understand the importance and the relationship of the establishment design and facilities to drug hygiene.
2. Ensure adequate and appropriate personal, maintenance and sanitation programs
3. To introduce to the trainees the key aspects regarding process control system
4. To introduce the trainees to the documentation and records requirements including lot identification and product complaint and recall systems.

LEARNING OUTCOME
After completing this course, the participants should be knowledgeable on: all Good Manufacturing Practice elements for the manufacturing of active pharmaceutical ingredients (APIs) under an appropriate quality management system to ensure that the finished products meet the requirements for product quality and purity.

WHO WILL BENEFIT:

1. Regulatory and Quality assurance government personnel (inspectors).
2. Plant operational (production) supervisors and managers
3. Middle-to-senior management
4. Newly hired plant technicians

LENGTH
One business day (seven hours)

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

HANDOUT MATERIALS
A binder that contains the training slides

SOURCES AND GUIDELINES
The following sources constitute the basis of this training program:

1. Canadian Food Inspection Agency (CFIA), Food Safety Enhancement Program (FSEP) Implementation Manual, Volume 2,
2. Drug Good Manufacturing Practices (GMPs) and Establishment Licensing (EL) Enforcement Directive (POL-0004)
3. Health Products and Food Branch Inspectorate: Good Manufacturing Practices Guidelines, 2002 Ed. Version 2
4. International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use; ICH harmonised tripartite guideline. Good manufacturing practice guide for active pharmaceutical ingredients (Q7).

CONTENTS

1. Premises (the building, facilities/utilities) and plant location
2. Equipments
3. Personal cleanliness, health status, behavior and visitors
4. Pest control systems, cleaning procedures and programs, and waste management
5. Introduction to operation control and elements of hygiene control systems
6. Examples of general control procedures and documentation and records requirements
7. Incoming material requirements
8. Packaging and labeling
9. Product complaint and recall procedures

COURSE PRICING
Please refer to the training page on our website.

CERTIFICATIONS
Trainees who participate in this program will receive a “Certificate of Completion” from QMRS.

For more information, please contact:

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