

GOOD DOCUMENTATION PRACTICES TRAINING COURSE

OBJECTIVES:

The objective of this course is to provide the trainees with a comprehensive understanding of the Good Documentation Practices (GDPs) definition and requirements.

LEARNING OUTCOME

After completing this course, the participants should be knowledgeable on

1. How to develop and keep documents on his/her organization Quality Management System,
2. How to establish documents on product requirements (specifications),
3. How the facility document (File) activities and processes (procedures),
4. And how one can establish objective evidence for activities performed or results achieved (Records).
5. Participants will learn also the basic writing skills, and. step-by-step description of how to write SOPs and policy in an informative manner.

WHO WILL BENEFIT

1. Regulatory and quality assurance personnel
2. Quality systems auditors
3. Marketing personnel
4. Operational managers
5. Middle-to-senior management

LENGTH:

One day.

INSTRUCORS

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

HANDOUT MATERIALS

A training binder with samples of well written SOPs

SOURCES AND GUIDELINES

The following sources constitute the basis of this training program:

1. American National Standards. Quality Management System (Fundamentals and Vocabulary, and QMS. ANSI/ASQ Q9000:2000 and ANSI/ASQ Q9001:2000.
2. Good manufacturing practices for pharmaceutical products: main principles. In: WHO Expert Committee on specifications for Pharmaceutical Preparations. (WHO Technical Report Series, No. 9 08).

CONTENTS

1. Concepts relating to documentation and value of documentation
2. Types of documents that used in Quality Management System
3. Documents property and categories
4. Documents format and management
5. Writing skills Basics
6. Templates design
7. Documents development process and control
8. Processes documentation identifications and requirements
9. FDA Dietary Supplement Rules documentation requirements
10. GMPs documents needed by Health Canada
11. **QMRS** documentation characteristics and benefits.

COURSE PRICING

Please refer to the training page on our website.

CERTIFICATION

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

For more information, please contact:

Quality Medical Regulations Services
(QMRS)
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