



Ministry of Health & Population
Egypt

Pharmaceutical Sector Reform Program HSRP

Pharmaceutical Training Program in collaboration with Europe Aid

Identification Number: EuroAid/121454/D/SV/EG

Program Specifications

Program 1: Quality Assurance & Auditing in the Drug Sector

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1. General Objectives

To provide the participants with basic concepts and elements of Quality Assurance of medicines, concepts of Total Quality Management and Quality System as well as limits of their application in drug manufacturing plants, community pharmacies, hospital pharmacies, warehouses and stores, and scientific laboratories.

Furthermore, the program aims at providing the participants with the ability to solve problems which they may face in the field.

Moreover, the program aims at providing the participants with the ability to conduct auditing using universally accepted tools and techniques in different situations.

2. Intended Learning Outcomes (ILOs) of the program

2.1. Knowledge/Understanding

By the end of this program the trainee should be able to demonstrate understanding of:

- 2.1.1. The principle of manufacturing pharmaceutical products so as to ensure that they are fit for their intended use, comply with the requirements of the marketing authorization and do not place patients at risk due to inadequate safety, quality or efficacy.
- 2.1.2. The interrelationship basic concepts of Quality Assurance (QA), Good Manufacturing Practice (GMP) and Quality Control.
- 2.1.3. The responsibility of senior management and the necessity of the participation and commitment by staff in all departments at all levels in the company for the attainment of the quality objective.
- 2.1.4. The basic elements of Quality Assurance in:
 - 2.1.4.1. Design and development of pharmaceutical products.
 - 2.1.4.2. Production and control operations.
 - 2.1.4.3. Process and in-process controls.
 - 2.1.4.4. Validation of process and qualification of equipment and systems as well as calibration of measuring instruments
 - 2.1.4.5. The responsibility of the authorized person in the release of finished products.

2.1.4.6. Storage and distribution of pharmaceutical products so as to maintain their quality throughout their shelf-life.

2.1.4.7. Self-inspection and/or quality audit for regular appraisal of the effectiveness and applicability of the Quality Assurance System

2.2. Intellectual Skills

By the end of this program the trainee should be able to:

2.2.1. Evaluate the GMP-compliance of a manufacturing plant or any other establishment handling pharmaceutical products.

2.2.2. Appreciate the interrelationships of GMP, Quality Control and Quality Assurance as essential elements of a Quality System.

2.3. Professional and Practical Skills

By the end of this program the trainee should be able to:

2.3.1. Handle In-process Control results, laboratory findings in a scientific way to assess correctness.

2.3.2. Solve quality-related problems by tracing root causes through meticulous reviewing of batch documents, environmental monitoring records and other documents.

2.3.3. Use of appropriate investigations in relation to GMP non-conformances and other quality-related shortcomings to find out their causes and suggest rational corrective actions.

2.4. Transferable Skills

By the end of this program the trainee should be able to:

2.4.1. Advise his/her surroundings to avoid quality-related problems and GMP non-conformances.

2.4.2. Adopt the Zero-defect principle, i.e. to prepare well for every activity to do it right the first time.

3. Program Contents

Topics

- 3.1. Restructuring Strategies of the Pharmaceutical Sector as Part of the Health Sector Reform.
 - 3.1.1. Functional Restructuring and its Rationale.
- 3.2. Good Manufacturing Practice (GMP) and the Concept of Quality Assurance (QA).
 - 3.2.1. Premises & Facilities.
 - 3.2.2. Equipment & Personnel.
 - 3.2.3. Documentation in Pharmaceutical Industry.
 - 3.2.4. Standard Operating Procedures (SOPs).
- 3.3. Validation.
- 3.4. Risk Analysis & Hazard Analysis & Critical Control Point Methodology (HACCP).
- 3.5. Total Quality Management (TQM).
- 3.6. Quality System Analysis.
 - 3.6.1. Personal Hygiene & Sanitation.
 - 3.6.2. Contamination, GMP & Personal Hygiene – Case Study.
 - 3.6.3. Cross Contamination & Mix Up – Case Study.
 - 3.6.4. Corrective & Preventive Action (CAPA).
- 3.7. Good Laboratory Practice (GLP).
 - 3.7.1. Policies in the Health Sector with Particular Emphasis on Pharmaceutical Sector.
 - 3.7.2. Accreditation of Laboratories.
- 3.8. Counterfeit Pharmaceuticals.
 - 3.8.1. Good Trade & Distribution Practices.
- 3.9. Good Storage Practice (GSP).
- 3.10. Change Control.
- 3.11. Auditing Procedures & their Application in the Drug Sector¹.

¹ This topic will be touched upon in a brief way in this program, but it will be handled in more details in Program 2 (Drug Inspection).

It is advisable that participants of program 1 should also participate in Program 2

4. Training and Learning Methods

- 4.1. Interactive training including mini-lecture, brainstorming, case study, role-plays, open discussion, and presentations delivered by qualified expert trainers.
- 4.2. Small group work
- 4.3. External readings
- 4.4. Detailed trainees handouts.

5. Assessment/Indicators

- 5.1. Class and group participation (25%)
- 5.2. Presentation and open discussion exercises (30 %)
- 5.3. On time delivered homework (20 %)
- 5.4. Pre vs. post tests (25 %)

6. Target Groups

- 6.1 Pharmacists
- 6-2 Inspectors
- 6-3 Drug Researchers

7. Number of Participants

Twenty Participants

8. Duration

10 Days (50 Hours)

9. References

- 9.1. Good Manufacturing Practices for Pharmaceutical Products: main principles
WHO Technical Report Series, No. 908, 2003 pp 36-89
- 9.2. Quality Assurance of Pharmaceuticals
A Compendium of Guidelines and Related Materials, vol. 2, WHO, Geneva, 2004
- 9.3. Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals
WHO Technical Report Series, No. 908, 2003
- 9.4. Guide to Good Storage Practices for Pharmaceuticals
WHO Technical Report Series, No. 908, 2003 pp 125-136
- 9.5. Guide to Good Manufacturing Practice for Pharmaceutical Products
PIC/Scheme July 2004