



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 2: Drug Inspection

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1. General Objectives

To develop and upgrade knowledge and skills of pharmaceutical inspectors and others whose duties necessitate conducting inspections. The program addresses a number of aspects that should be mastered by inspectors, such as laws and regulations, inspection techniques and working procedures. It also addresses inspection reporting and documents used in inspection. Furthermore, the program addresses Check-Lists and "Aide Memoire" used in conducting inspection, communication skills and inter-personal relationships. It finally addresses the attributes of successful inspectors. Ways and means of fact finding and interpretation will be handled.

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 laws and regulations in drug sector.
- 2.1.2. The rationale of governmental inspection and its role in assuring the quality of medicines.
- 2.1.3. The role of inspection in combating substandard and counterfeit drugs.
- 2.1.4. The advantages and disadvantages of using Check-Lists or "Aide Memoire" during inspection

2.2. Intellectual Skills:

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

- 2.2.1. Evaluate GMP – violations which compromise quality.
- 2.2.2. Evaluate genuineness of documents and whether they are fake or forged.
- 2.2.3. Evaluate character and honesty of persons interviewed during inspection.
- 2.2.4. Judge compliance of environmental conditions with GMP – requirements.
- 2.2.5. Face problems and obstacles which may arise during inspection.

2.3. Professional/Practical Skills:

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

- 2.3.1. Master appropriate techniques for fact finding during inspection.
- 2.3.2. Avoid distractions which may cause delay or hindrance of the inspection.
- 2.3.3. Judge quality – related problems objectively and to judge the suitability of solutions used for these problems.
- 2.3.4. Use documents properly such as Check-Lists or “Aide Memoire” and how to write reports and corrective action plans after completion of the inspection.
- 2.3.5. Face challenges during inspection, be it objective, i.e. work-related, be it subjective, i.e. caused by the inspected unit.
- 2.3.6. Advise the inspected units on quality – related issues and suggest corrective actions and adequate means for effective follow-up

2.4. Transferable Skills:

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

- 2.4.1. Adopt a firm and resolute attitude to prevent any compromising of quality.
- 2.4.2. Take suitable measures to prevent substandard & counterfeit goods from reaching the consumers.

3. Program Contents:

Topic

- 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. Legal Framework of Pharmaceutical Systems of Inspection.
- 3.3. Technical Aspects of Pharmaceutical Systems of Inspection.
 - 3.3.1. Auditing Procedures & their Application in the Drug Sector Governmental Inspection.
- 3.4. Total Quality Management (TQM).
- 3.5. Inspection.
 - 3.5.1. Pre-approval.
 - 3.5.2. Inspection of Pharmaceutical Manufacturers.
 - 3.5.3. Regulatory Actions.

- 3.5.4. Standard Operating Procedures (SOPs) for Preparing an Inspection & for Performing it.
- 3.5.5. Inspection Procedures.
- 3.6. Documentation of Inspection
 - 3.6.1. Inspection Checklists.
 - 3.6.2. Inspection Reporting.
- 3.7. Inspection of Quality System.
 - 3.7.1. Inspection of Quality System for Water for Pharmaceutical Use.
 - 3.7.2. Inspection of Quality Control: Hygiene & Sanitation.
 - 3.7.3. Inspection of Quality Control Laboratory.
 - 3.7.4. Corrective & Preventive Actions (CAPA).
- 3.8. Quality System Requirements for GMP Inspectorates.
- 3.9. Inspection of Establishments (Starting Manufacture).
 - 3.9.1. Validation Master Plan (VMP).
 - 3.9.2. Site Master File.
 - 3.9.3. Inspection of Sterile Drug Substance Manufacture.
 - 3.9.4. Inspection of Retail Pharmacies & Warehouses.

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. Homework exercises including preparation of presentation material.
- 4.4. External readings.
- 4.5. 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. Pharmaceutical inspectors.
- 6.2. Laboratory researches in NODCAR.

7. Number of Participants:

Twenty Participants

8. Duration:

10 Days (50 Hours)

9. References:

Various WHO Publications