Drug and Therapeutics Committee
Training Course

Session 5.
Pharmaceutical Quality Assurance

Trainer’s Guide
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Developed in Collaboration with the  
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ABBREVIATIONS AND ACRONYMS

COA certificate of analysis
DTC Drug and Therapeutics Committee
GMP Good Manufacturing Practices
mcg microgram
mg milligram
ml milliliter
ng nanogram
QA quality assurance
UNICEF United Nations Children’s Fund
UNIPAC UNICEF Supply Division Warehouse Procurement and Assembly Center
VA visual aid
SESSION 5. PHARMACEUTICAL QUALITY ASSURANCE

Purpose and Content

The Drug and Therapeutics Committee (DTC) is the cornerstone of a health care organization’s medicine use and distribution program. This committee has many different functions that will contribute significantly to the goal of improving medicine selection and rational use of medicines. Session 5 provides an overview of medicine quality and the responsibilities of the DTC for assuring that high-quality products are obtained for the formulary.

Objectives

After attending this session, participants will be able to—

- Define medicine quality
- Understand how medicine quality is assessed
- Understand how medicine quality is ensured
- Describe the role of the DTC in pharmaceutical quality assurance

Outline

- Key Definitions
- Introduction
- Determinants of Medicine Quality
- How is Quality Assessed?
- How is Quality Assured?
- Important Pharmaceutical Quality Issues for the DTC
- Implications for the DTC

Preparation and Materials

Read the Trainer’s Guide and the Participants’ Guide and review the visual aids (VAs).

Further Readings


Visual Aid Listing

1. Title slide
2. Acknowledgment
3. Objectives
4. Outline
5. Key Definitions (1)
6. Key Definitions (2)
7. Introduction: Goals of Medicine Quality Assurance Programs
8. Characteristics of a Comprehensive QA Program (1)
9. Characteristics of a Comprehensive QA Program (2)
10. Impacts of Low-Quality of Medicines
11. Determinants of Medicine Quality
12. Potential Bioavailability Problems
13. Standard Method for Bioavailability Studies
14. Rifampicin 450 mg Capsules: > 100% Variation among Brand Names
15. Captopril 25 mg: Variation among Brand Names
16. Nifedipine 20 mg: Generic vs. Brand Name
17. Slow-Release Diclofenac Tablet
18. Medicines with a Stability Problem
19. How is Quality Assessed?
20. How is Medicine Quality Assured? (1)
21. How is Medicine Quality Assured? (2)
22. How is Medicine Quality Assured? (3)
23. How is Medicine Quality Assured? (4)
24. Who Ensures Medicine Quality?
25. Implications of Pharmaceutical QA for the DTC
26. Activity
27. Summary (1)
28. Summary (2)
29. Summary (3)
Organization of the Session

Total time: 3 hours

Session 5 is intended to provide the participants with basic information about assessing and managing pharmaceutical quality issues. Many participants may feel that quality assurance (QA) is not their problem and that other departments are responsible for this area. The message of session 5 is that QA is the responsibility of everyone: DTC, providers, pharmacists, procurement officials, and patients. You will need to convince the participants early in the session that a DTC should be concerned with quality issues so that the participants will be able to make the most of the session activity using presentations from their own home situations.

You will need a substantial working knowledge of pharmaceutical QA, procurement, storage, and distribution practices to facilitate this session.

First component: 10 minutes
VAs 1–6: Introduction

Introduce the session by asking participants what their specific concerns are about medicine quality. What types of problem occur and why in their home countries? Afterward carefully go through the definitions.

Second component: 20 minutes
VAs 7–11: Medicine Quality Assurance Programs

Point out the two main goals of a comprehensive QA program—

- *Obtaining* quality products that are safe and effective through structured selection and procurement methods
- *Maintaining* quality products through the appropriate storage, distribution, monitoring, and prescribing methods

Discuss the important components of a comprehensive QA program. It is unlikely that many of the physicians (and also some of the pharmacists) would be this involved in QA or realize that they should be. Ask the participants to describe the various problems that can occur with poor quality medicines and all the various consequences. The subsequent discussion should lead to more interest by the participants in obtaining better QA programs.

Discuss the determinants of medicine quality, and use pharmacopoeia standards as examples

Third component: 30 minutes
VAs 12–18: Problems of Bioavailability and Stability

Define *bioavailability* before starting the discussion: bioavailability refers to the speed and completeness with which an administered medicine enters the blood stream.
Explain that bioavailability must be consistent to provide a predictable therapeutic result. Medicine bioavailability differences exist between manufacturers of the same product. Therefore, careful evaluation of generic medicines may be necessary before purchase and use.

Obtain participant feedback concerning this well-known problem. Encourage discussion within the groups so that all can learn from others concerning this important and controversial issue.

**Caution:** Obtaining bioavailability information is difficult, and it is frequently inaccurate or difficult to interpret.

Acknowledge that the slides were provided by Suryawati and Santoso of Indonesia.

Define *stability:* The activity of the medicine is ensured for the period of time stated on the product label, that is, until the expiration date. Explain that stability is a particular problem in hot and humid climates.

**Fourth component: 30 minutes**  
*VAs 19–25: Assuring Medicine Quality*

Ask how many participants actually do laboratory testing at their facilities. How much does it cost? Discuss the need for obtaining bioavailability data and the difficulty in obtaining this important information.

Ask how many participants actually do structured procurement with prequalified suppliers. This particular aspect of procurement will reduce the number of low-quality products by screening out suppliers with a poor history of service and quality.

Reinforce to all the participants the need to be involved at all levels of the health care system to ensure that quality medicines are made available.

**Fifth component: 60 minutes**  
*VA 26: Activity*

The rationale for this activity is for the participants to identify the scope and extent of individual participant and DTC responsibilities for pharmaceutical QA. This activity will give participants the opportunity to discuss their medicine quality programs and concerns and to provide input for solutions of other participants’ problems.

Participants should list the specific QA concerns in their programs in hospitals and primary care clinics. List them under the following headings—

- Obtaining quality products (source issues): problems with the quality of medicines being supplied by commercial sources, government production, or donors
- Maintaining quality products (supply system issues): problems with quality assurance at the central warehouse, in transit, at local facilities, and the like
- Examples of poor quality: anecdotes illustrating poor quality that do not clearly fit under the above headings

As a part of this exercise, ask the participants to answer the following questions concerning their QA programs—

1. Are you satisfied with the quality of medicines you receive?
2. Is quality maintained throughout your distribution network?
3. Are there complaints of poor quality by patients or health workers?
4. Is there a formal mechanism for reporting and investigating product quality complaints?
5. What role do you see for the DTC in improving and maintaining quality in your health care system?
6. Does anyone have a particular quality assurance issue with which he or she needs help?

**Sixth component: 10 minutes**

**VAs 27–29: Summary**

Summarize the key points of the session. Remind everyone that—

- Poor medicine quality produces poor patient outcomes, increases cost, erodes credibility for the entire health system, and decreases confidence in health care staff and patients

- Medicine quality is the responsibility of everyone and the DTC is in a position to supervise overall pharmaceutical quality assurance