

QUALITY ASSURANCE /QA/ FOR DRUG PROCUREMENT

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Outline

At the end of this chapter, students will be able to:

- Describe drug quality and its objectives
- Describe the technical and managerial activities of QA
- Define and assess drug quality
- Identify consequences of poor drug quality
- Set priorities in quality assurance
- Identify critical elements in QA for drug procurement
- Identify determinants of drug quality
- Understand WHO certification scheme
- Describe counterfeit drugs and testing methods
- Understand Monitoring and evaluation.

Drug quality

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- Drug quality is assessed as product compliance with pharmacopoeia specifications concerning its identity, purity, potency, uniformity of dosage forms, bioavailability, and stability
- Drug quality is affected by
 - Manufacturing process
 - Packaging
 - Transportation and
 - Storage conditions which may have cumulative influences

Drug quality...

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- The quality of a final drug product is determined by
 - The raw ingredients
 - Equipment and
 - Technical know-how that goes into producing and packaging it
- NB: Quality assurance in drug supply is not the same as quality control in manufacturing

Objective of QA

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- To ensure that each drug reaching to a patient is **safe, effective, and of standard quality**
- A comprehensive quality assurance program includes
 - **Technical and managerial activities**, spanning the entire supply process from **drug selection** to **patient use**

Drug quality...

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Technical activities (laboratory testing):

- ❑ Evaluating pharmaceutical product documentation
- ❑ Performing or reviewing quality control laboratory test
- ❑ Monitoring product performance

Drug quality...

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Managerial activities:

- ☐ Evaluation and registration
- ☐ Selecting suppliers
- ☐ Proper transportation
- ☐ Monitoring supplier performance
- ☐ Enforcing drug inspection procedures throughout the distribution net work
- ☐ Post marketing surveillance (adverse drug reaction and defective drug reporting)

Consequences of poor drug quality

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- If a drug doesn't meet established quality standards, reaches its expiry date, or has been spoiled by local storage conditions, the possible consequences are:
 - Lack of therapeutic effect leading to death or prolonged illness
 - Toxic and adverse reactions
 - Waste of limited financial resources
 - Loss of credibility of the health care delivery system

Mechanisms to ensure drug quality

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- A comprehensive quality assurance program must ensure that:
 - Drugs be selected on the basis of safety & efficacy, in a dosage form with the longest possible shelf life
 - Suppliers with acceptable quality standards should be selected
 - Drugs received meet specified quality standards at the time of delivery

Mechanisms to ensure drug quality...

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- Packaging meets contract requirements and can withstand handling and storage conditions
- Repackaging activities and dispensing practices maintain quality
- Storage and transportation conditions should be adequate
- Drug recall procedures should be implemented to remove defective products

Setting priorities in quality assurance

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- Since resources are limited, priorities for quality assurance activities should be targeted
- **VEN method:** helps identify a small group of drugs that have the **greatest health impact**
- **ABC analysis:** can be used to identify those drugs that have the **greatest budgetary effect** if their quality is unacceptable

Criteria for close monitoring of drugs

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- ❑ Drugs with low (narrow) therapeutic indices
- ❑ Drugs with inherent bioavailability problems
- ❑ Sustained release preparations
- ❑ Drug products from new suppliers and suppliers with problems in the past
- ❑ Drugs that require stable dosage forms and appearance

Critical elements in QA for drug procurement

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1. Product selection

- Products with longer shelf life (for example, powders for reconstitution rather than oral suspensions)
- Avoidance of products with the bioavailability problem, when possible.

Critical elements in QA...

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2. Supplier selection

- ❑ Supplier prequalification
- ❑ Recent GMP inspection reports from national drug authorities
- ❑ Formal supplier monitoring system
- ❑ Limitation of purchases from new supplier to non critical products

Critical elements in QA...

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3. Product certification

- ❑ Current GMP certificate from drug regulatory authority
- ❑ Certificate of pharmaceutical products for all new products, new suppliers
- ❑ Batch certificate for problem drugs only

Critical elements in QA...

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- 4. Contract specifications:** detailed specifications to ensure that high quality drug products are bought and received include
- Acceptable pharmacopoeia standards
 - Language for the product label
 - Minimum information required on the label (generic name, dosage form, strength, quantity, expiration date, manufacturer, batch number)

Critical elements in QA...

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- Product registration and date of manufacturing
- Packaging standards that will withstand the specific storage and transport conditions

5. Inspection of shipment

- Physical inspection of all shipments
- Sampling for analysis of suspected products

Critical elements in QA...

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6. Targeted laboratory testing: laboratory testing is costly in terms of technical human resources, equipment, and reagents.

- Guidelines should target sampling to products that
 - Therapeutically critical drugs
 - Drugs with known bioavailability problems
 - New suppliers
 - Suppliers with quality difficulties in the past

7. Product problem reporting systems for suspect or problem products

WHO certification scheme

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- ❑ Drugs intended for export have not always been subjected to the same control procedures as those produced for the home market
- ❑ Developing countries, lacking adequate drug regulatory systems and laboratory facilities for drug analysis, are particularly disadvantaged
- ❑ Used as a means of exchanging information between regulatory authorities in importing and exporting countries (1975)

Objectives of WHO Certification Scheme

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1. To provide assurance that the plant in which the ***product is manufactured is subject to inspections*** at suitable intervals and conforms to the requirements for good practices in the manufacture and quality control of drugs , as recommended by WHO.

Objectives of WHO...

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2. To provide assurance that a given product has been ***authorized to be placed on the market*** in the exporting country and, if not, to explain why authorization has been withheld.
3. To provide for ***exchange of information*** on the implementation of inspections and controls by the authorities in the exporting country.

Counterfeit drugs

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- Refers to drug products with
 - Insufficient quantity of active ingredients or none, which results in the reduction of the drug products safety, efficacy and quality
 - Misabeled with respect to identity and /or source (ingredients that are not on the label, which may or may not be harmful)
 - Improperly processed within the body (e.g., absorption by the body)

Counterfeit drugs...

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- Counterfeit product looks like the real drug product
 - It is difficult even for the professionals to differentiate from the authentic one
- The problem of counterfeiting also exists in developed countries
- But counterfeiting is common in developing countries, where in most cases, there exists:
 - Absence of or insufficient drug regulatory agency
 - Absence of or weak information exchange mechanism

Counterfeit drugs...

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- ❑ No system of quality assurance (quality control laboratory, system of registration and inspection is lacking);
- ❑ Unregulated markets and distribution channels
- ❑ Corrupted system
- ❑ Absence of an explicit legislative authority or framework to address counterfeits

Counterfeit drugs...

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- ❑ Relaxed boarder controls or ineffective controls at ports of entry and distribution channels
- ❑ Lack of coordination among controlling bodies, such as, police, customs office, ministry of health, and other concerned bodies

Forms of counterfeiting drug products

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1. Fake labeling

- ❑ Placing a product on the market with out active ingredient
- ❑ Made available and marketed bearing the name, address and other marks of a famous and reputable manufacturer
- ❑ Placing a product on the market with insufficient quantity of active ingredients but labeled as if it contains full strength or with different label

Forms of counterfeiting...

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2. Brand imitation:

- The drug product may contain the real active ingredient but is marketed with the **brand name of another market leading product** of a well known manufacturer

3. Fake packaging:

- The product may be placed into the market with **exactly the same package design** of a product that has been well known in the market

Who are the victims of counterfeit drugs?

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1. Customers:

- ❑ Counterfeit drug products put the health and even the life of the customers at risk
- ❑ They are certainly exposed to unnecessary drug adverse effects and incur unnecessary expense

2. Governments are victims

- ❑ B/c they may fail to materialize their objective of protecting the public health, results in a decline in fiscal revenue, or citizens may complain on the system of administration and as a result lose their confidence on the governments' system.

Who are the victims ...

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3. **Health professionals:** customers may lose their confidence on the services provided by health professionals if the prescribed and dispensed drug products fail to perform the intended use.
4. **Legitimate manufacturers and/or distributors:** their reputation and image may be damaged if their products are counterfeited, and placed on the market.
 - They are also exposed to direct loss of revenue because producers or distributors of counterfeit drug products share the market.

Simple tests to detect counterfeit drug products

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- Testing the quality of drug products by means of **Minilab** involves the following test procedures:
 1. ***Visual inspection*** scheme of solid dosage forms including the associated packaging material for a timely rejection of rough counterfeits
 2. Simple tablet and capsule ***disintegration tests*** for a preliminary assessment of deficiencies related to drug solubility and bioavailability

Simple tests to detect counterfeit...

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3. Simplified ***color reactions*** for a quick check or any drug present, thus ensuring the drug's identity; and
4. Easy-to-use ***thin layer chromatography assays*** for a quick check of quantities of drug present, thus ensuring the drug potency.

Monitoring and evaluation

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Sample indicators:

- ❑ Adherence to the procurement time table
- ❑ Consideration of lead time
- ❑ Availability of significant amount of defective drug products
- ❑ Use of informative drug requisition
- ❑ Whether or not drugs are stored properly in accordance with the recommended storage conditions

THANK YOU !!!