

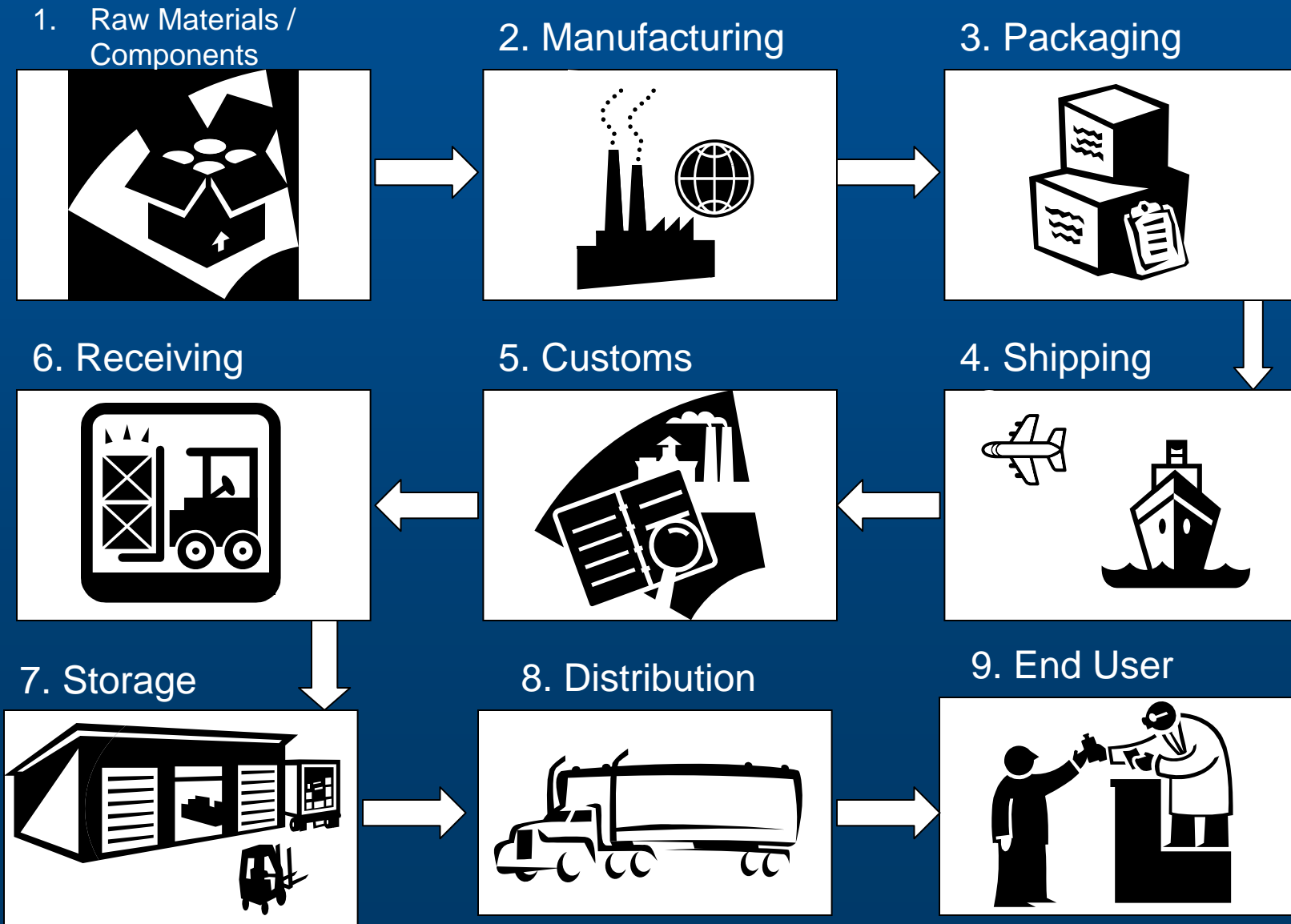
Session 4: Ensuring Product Quality Throughout the Supply Chain



World Health
Organization



Potential Quality Assurance Checkpoints Within the Overall Supply Chain



Key Players



National regulatory authority

Manufacturer

Raw materials suppliers

Logistics system

Procurement unit

End user



Roles and Responsibilities in Mitigating Product Quality Risks

Raw Materials Supplier

- Adheres to specifications / pharmacopoeial standards and cGMP
- Performs quality control and related tests throughout their manufacturing process
- Performs stability testing and certification of raw materials
- Compiles Drug Master File or provides relevant API information for product dossiers updates

Manufacturer

- Adheres to product specifications and/or pharmacopoeial standards and current Good Manufacturing Practices (cGMP)
- Performs relevant quality control and tests throughout the process
- Determines stability and product shelf life
- Has a system to track and respond to complaints and adverse events
- Complies with current regulatory standards

National Regulatory Authority

Role, capacity, and authority varies among countries. The following are typical NRA activities:

Enforces national medicines legislation and regulations, to guide:

- Which products are to be regulated
- Which companies / institutions are to be regulated
- Which activities are to be regulated
- To what extent the above will be regulated in the country, and who is responsible for what, and
- Which sanctions will apply in the case of violations

National Regulatory Authority

(continued)

- Set national standards for product development and testing
- Inspects and licenses manufacturers, wholesalers, distributors, etc.
- Authorizes and supervises clinical testing
- Evaluates the quality, safety, and efficacy of products
- Issues and maintains marketing authorizations
- Provides unbiased medicines information on authorized products, and controls promotion of products

National Regulatory Authority

(continued)

- Verifies product quality through laboratory testing
- Monitors the safety of products in use (adverse drug reactions and other information on product safety, product vigilance, pharmacovigilance)
- Monitors product complaints
- Takes remedial actions if necessary

Procurement Unit

- Applies appropriate quality standards in sourcing, procurement, and distribution, for example:
 - Apply internationally agreed standards such as GMP, GDP
 - Pre-qualify and/or post-qualify suppliers
 - Evaluates product information and contractually enforces the right to inspect sites and test goods
 - Specifies alternative shelf-life requirements to suit local climatic conditions as appropriate
 - Act as mediator between manufacturer and end-users in case of complaints and product failures

Logistics System

- Applies appropriate shipping and handling instructions to ensure product integrity
- Enforces product quality requirements by product batch prior to shipment, either through documentation or pre-shipment inspections
- Provides a storage environment that is GDP compliant and/or ISO compliant
- Manages product expiry dates through appropriate inventory control systems

End User

- Performs visual inspection of product
- Properly stores product
- Checks product expiration date
- Reports complaints

What other international standards and norms exist to help ensure product quality?

Additional Standards for Ensuring Product Quality

- **Good Procurement Practices**
- **Good Distribution Practices**
- **Good Laboratory Practices**
- **Good Dispensing Practices**
- **ISO Standards, CE Markings**

Quality Assurance Overview

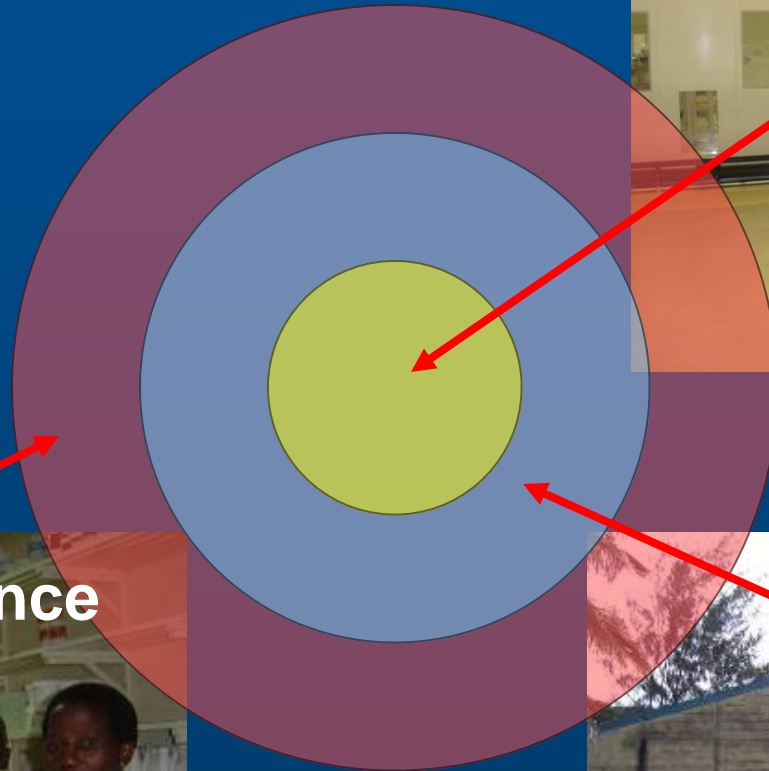


Photo: Ousmane Dia, JSI



Photo: Lisa Hedman, PATH



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Benefits of QA systems

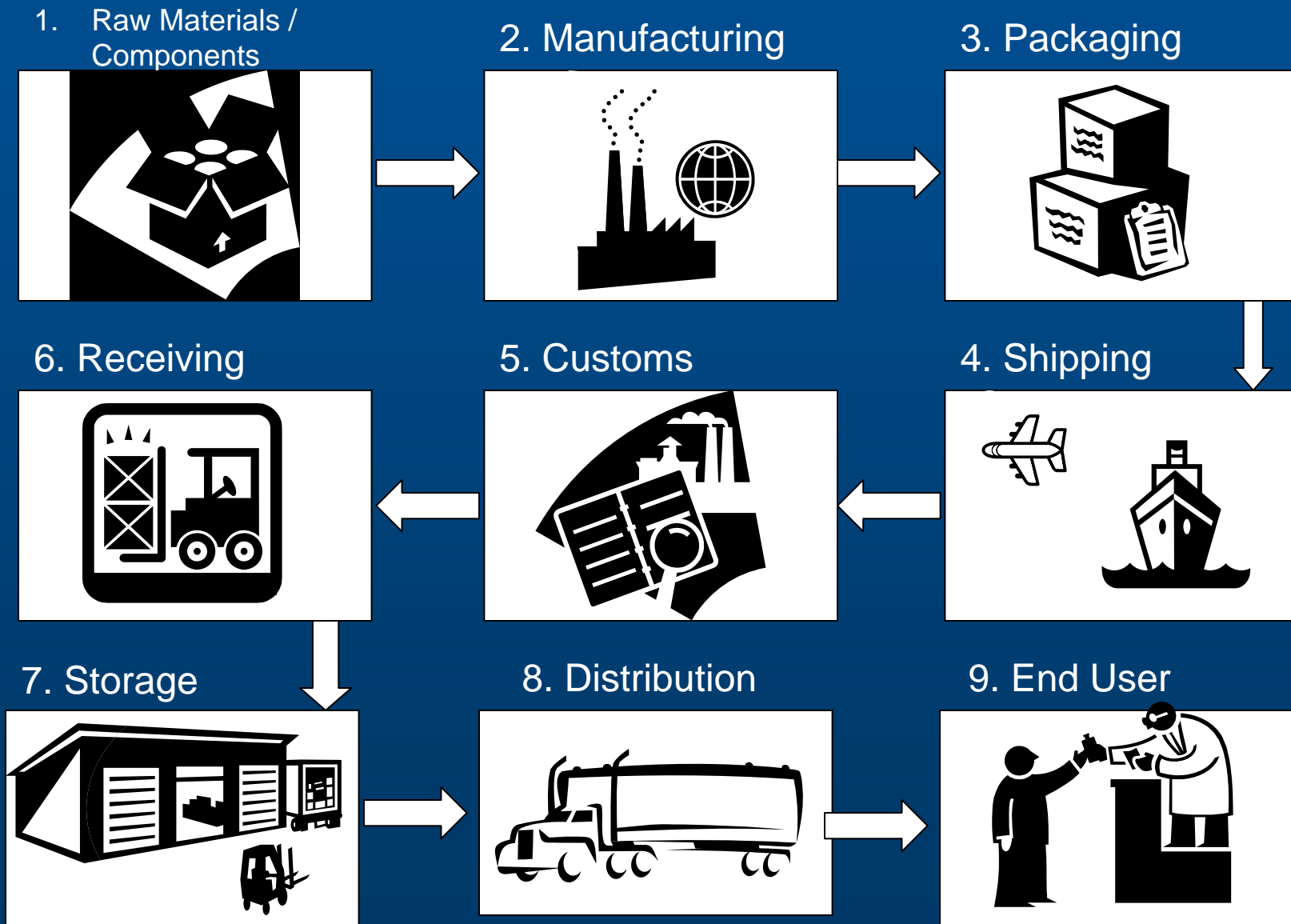
- Ensuring good-quality medicines that provide the intended effect
- Ensuring that financial resources are not wasted on poor-quality products
- Increasing confidence in the ability to provide good-quality products
- Improving a manufacturer's ability to produce good-quality products

Group Exercise

Key Procurement Responsibilities

1. Participants divide into four groups. Each group will be assigned two of the key activities identified in the supply chain graphic as follows:
 - Group A: Raw Materials/Components & Production**
 - Group B: Packaging & Shipping**
 - Group C: Customs & Receiving**
 - Group D: Storage & End User**
2. Using a T bar for each activity, the group will identify potential QA problems for the activity on the left side of the T bar. On the right side, identify the corresponding measures and the responsible party for addressing the QA problem.

Potential Quality Assurance Checkpoints Within the Overall Supply Chain



Procurement Role in Quality Assurance in the Supply Chain Small Group Exercise

Instructions to participants:

1. Divide into four groups.
2. Each group will be responsible for evaluating two of the key supply chain activities to identify quality assurance (QA) problems as follows:
 - Group A: Raw Materials/Components & Manufacturing
 - Group B: Packaging & Shipping
 - Group C: Customs & Receiving
 - Group D: Storage & Distribution/End User
3. Using a flipchart and a T Bar analysis approach as shown below, each group will brainstorm and identify QA problems for the key supply chain activities they are assigned, and list these on the left side of the T bar.
4. After the QA problems have been identified, the group should brainstorm and list on the right side of the T bar the recommended actions for a person in a procurement role to address each QA problem identified.
5. Take 20 minutes for the exercise in your small group.
6. Assign a spokesperson to report out to the larger group.

Raw Materials/Components & Manufacturing

QA problems	Recommended actions

Procurement Role in Quality Assurance in the Supply Chain Small Group Exercise

Answer Key

Raw Materials/Components & Manufacturing

QA problems	Recommended actions

Raw Materials/Components & Manufacturing

Problem:

- Poor quality, substandard raw materials
- Poor quality, substandard components

Recommended action for procurement

- Call out specific raw material specifications in purchase order
- Require submission of raw material certifications for product in purchase order
- Call out specific component specifications in purchase order
- Require component part certifications for product in purchase order

Manufacturing

Problem:

- Product not manufactured to performance and quality requirements

Recommended action for procurement

- Clearly identify performance and quality requirements in purchase order
- Include requirement for certification of current good manufacturing practices (cGMP) compliance in purchase order
- Include requirement for in-house batch analysis and internal quality control (QC) records in purchase order
- Reserve the right to conduct random sampling and independent testing of finished product prior to shipment in the purchase order

Packaging

Problem:

- Packaging not adequate to protect product during transport

Recommended action for procurement

- Call out specific unit packaging and requirements in purchase order
- Specify requirements for outer packaging in purchase order

ShippingProblem:

- Product damaged during shipment

Recommended action for procurement

- Specify shipping and handling requirements for product.

CustomsProblem:

- Clearance delayed due to missing documentation

Recommended action for procurement

- Coordinate with in-country end user to identify customs clearance requirements and identify documentation requirements in shipping instructions.

StorageProblem:

- Products not stored in required environmental conditions

Recommended action for procurement

- Specify outer package marking requirements to include specific storage instructions for product.

End UserProblem:

- Products not stored in required environmental conditions

Recommended action for procurement

- Specify unit package marking requirements to include specific storage instructions for product.