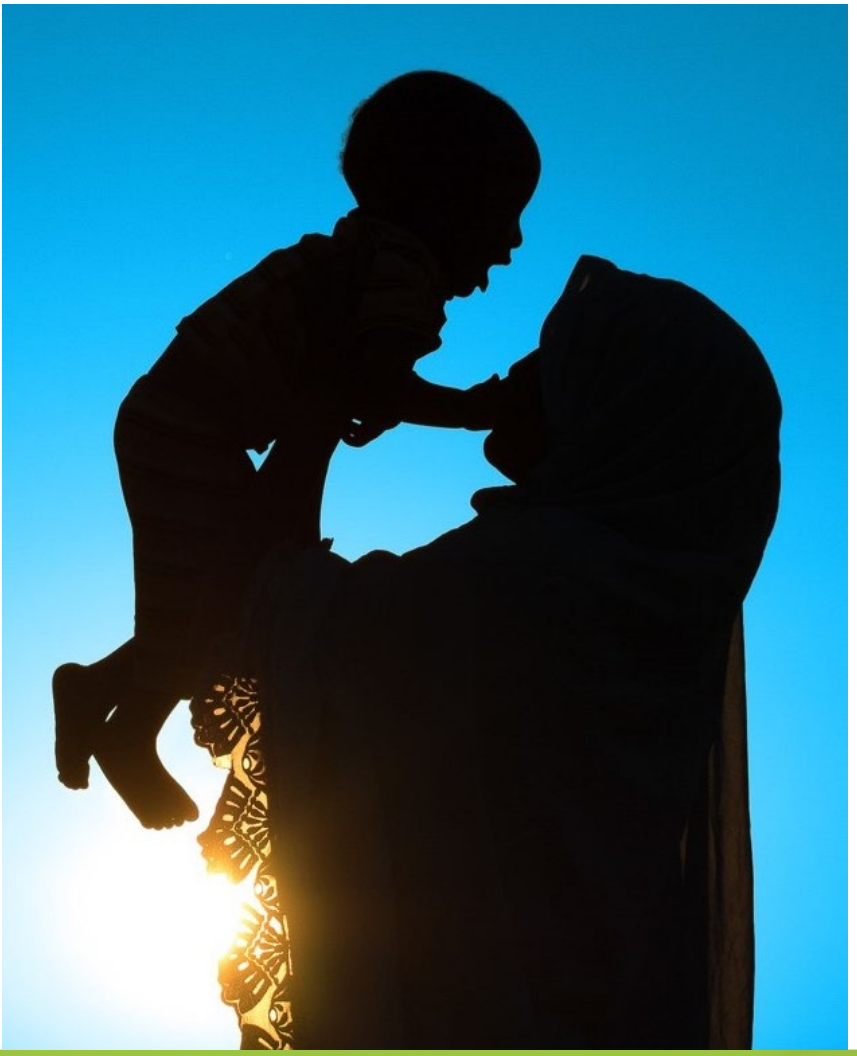

# BECOMING A SUPPLIER TO UNICEF

## Steps for successful engagement

## Quality Assurance for Pharma


**Presenters:**

**Unine Felix**
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**Quality Assurance Centre**
**UNICEF Supply Division**


**04 December 2024**

# UNICEF Quality Assurance Centre
## Core Activities

### Quality Management Unit:

Responsible for maintaining an effective and efficient Quality Management System (QMS) in UNICEF SD

- Documentation management System
- Quality Manual
- Complaints Management
- Recall Management
- CAPA Management
- Deviation Management
- Risk Management
- Internal Assessments

### Supplier Evaluation Unit:

Responsible for elements in vendor management, vendor evaluation, vendor registration, bids management, supplier performance monitoring etc.

- Bids receipt and registration, bid opening
- Vendor evaluation (ethical and financial)
- UNGM vendor registration
- Vendor Review Committee

### Quality Inspection Unit Non-Pharma:

Responsible for all audit inspections and evaluations carried out for non-pharmaceutical goods and services procured by UNICEF Supply Division (SD).

- Conformity Assessments
- Site Inspection
- Goods Receipt Inspection
- Pre-Delivery Inspection and Supervision of Loading
- Sample Evaluations

### Quality Inspection Unit Pharma:

Responsible for various elements of the UNICEF Quality Assurance System for pharmaceuticals and nutritional products.

- GMDP inspections
- GMDP evaluations
- GDP self-inspection
- GDP training
- Quality Control
- Goods Receipt Inspection
- Import and export authorizations for narcotics, psychotropic substances

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UNICEF Quality Management System (QMS):

- ❑Based on ISO 9001:2015
- ❑Documentation Management System include:
  - ▪UNICEF SD Division Procedures
  - ▪UNICEF SD Centre Procedures
  - ▪UNICEF SD Internal Guidelines
  - ▪UNICEF Regulatory Supply Documents across Supply Functions

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Vendor Evaluation:

- ❑ All UNICEF vendors are expected to register in UNGM https://www.ungm.org/
- ❑ Vendors screening include:
  - Ethical evaluation to obtain assurance that the vendor is not engaged in unethical conduct such as corruption, fraud, sexual exploitation or abuse, child labour, etc.
  - Financial position to mitigate associated risks like poor quality products, late delivery, insolvency, etc.
- ❑ Vendors involved in proscribed practices are referred to the Vendor Review Committee to decide on remedial action

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- ❑ Manufacturer audits and validation: trained QMS auditors
- ❑ Quality Control
  - Management of Pre-delivery inspections (PDI)
  - Sampling and Testing
  - Goods Receipt into the warehouse
- ❑ Sample evaluation
- ❑ Supply Division Quality Control laboratory

ISO 9001, 2015 QMS
ISO 13485, 2016 QMS Medical Devices
ISO 2859 Sampling Standard
ISO 14001 QMS Environmental Systems
SA 8000 Social Accountability
Products related standards

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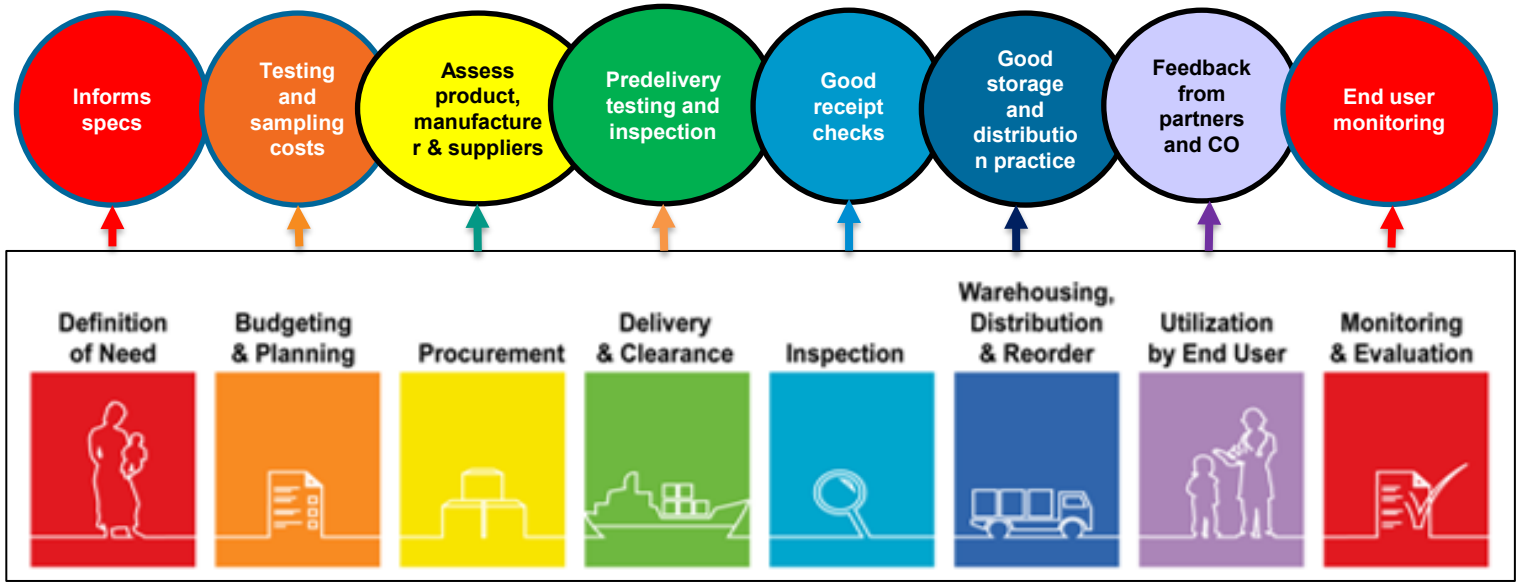
- ❑ GMDP requirements for *pharmaceutical products*
  - WHO GMP and GDP Guidelines for pharmaceuticals
  - National Guidelines where applicable
- ❑ GMP requirements for *nutritional products*
  - Codex Alimentarius, ISO 22000 for nutrition products, General Principles of Food Hygiene CXC 1-1969, Code of Hygienic Practice for Low Moisture Foods (and its Annexes) CXS 75-2016, Certification of Food safety management systems FSSC 22000
- ❑ GMP inspection frequency
  - Risk-based for pharmaceutical product suppliers
  - Every year for nutritional product suppliers
- ❑ WHO “Model Quality Assurance System for Procurement Agencies MQAS” - TRS 986 Annex 3 is used as a model for procurement of both nutrition and pharmaceutical products

# UNICEF Quality Assurance Centre
## QA Role in the UNICEF Supply Chain

Ensuring **quality products** are available for use

Requires **Quality Assurance** throughout the Supply Chain



# UNICEF Quality Assurance Centre
## Supplier & Manufacturer Qualification

## SUPPLIERS & MANUFACTURERS

### PREQUALIFICATION

**DESKTOP GMDP EVALUATION**

- Technical Questionnaire
- Site Master File *incl.* attachments
- Manufacturing and/or Wholesale License *incl.* attachments
- GMP / GDP certificates or ISO 22000 or equivalent *as applicable*
- Recent Inspection Reports *incl.* NRA and/or SRA

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# UNICEF Quality Assurance Centre
## Supplier & Manufacturer Qualification

## SUPPLIERS & MANUFACTURERS

## PREQUALIFICATION

### TECHNICAL QUESTIONNAIRE

Pharmaceutical **Manufacturers**

Pharmaceutical **Wholesalers**

**PURPOSE**

- ❑ To perform a GMDP evaluation of company using a quality risk management tool to determine:
  - The need for a GMP / GDP audit.
  - The frequency, scope and duration of the GMP / GDP audit.
- ❑ Forms part of the document assessment in preparation for a GMP / GDP audit.

# OTHER VENDORS

## FREIGHT FORWARDERS

- GDP inspections
- Contractual Agreements

## QUALITY CONTROL LABORATORIES

- WHO PQ Quality Control Laboratories
- Risk- based good laboratory practice inspections
- Contractual Agreements
- Periodic performance reviews

# SUPPLIERS & MANUFACTURERS

## GMDP INSPECTIONS

### PLAN

- Risk-based approach
- Using outcome of GMDP desktop evaluation
- Predicts criticality and inspection frequency
- Prepared yearly and reviewed twice yearly

### PREPARE AND PERFORM

- Agree on inspection date
- Request relevant documents for review upfront
- Provide inspection plan in advance
- Extend invitation to local authority
- Inspection performed by UNICEF inspector(s)
- Inspection report shared
- Corrective and Preventative Actions reviewed & agreed
- Closing Letter
- Outcome communicated within UNICEF
- If negative, supplier blocked and shared with Partners where necessary

# SUPPLIERS & MANUFACTURERS

## RELIANCE FRAMEWORK

### INTERNATIONAL COLLABORATION

- ❑ Interagency Joint inspections with WHO PQ, ICRC, MSF and WFP
- ❑ UNICEF is a Partner to the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
- ❑ Sharing inspection reports and information with international partners and vice versa
- ❑ UNICEF relies on WHO PQ of vaccines, HIV, Malaria and TB products
- ❑ Sharing of rapid-alert information *incl.* complaints, recalls & counterfeits

# QUALITY MANAGEMENT

## QUALITY CONTROL

### DIRECT SHIPMENTS

- Pre-delivery inspections (PDI)

### COPENHAGEN WAREHOUSE SHIPMENTS

- Visual Inspection
  - Product
  - Dosage form and strength
  - Quantity

- Certificate of Analysis
  - Satisfactory remaining shelf-life
  - Product manufactured by the approved site

- Annual Sampling & Testing Program
  - Risk-based selection
  - Contract laboratory WHO prequalified
  - Predelivery inspections for direct shipments

# QUALITY MANAGEMENT

## COMPLAINTS and RECALLS

### COMPLAINTS

- ❑ Dedicated complaints team
- ❑ Electronic database - CICA
- ❑ Complainant log directly into CICA
- ❑ Complaint categorized
- ❑ Solution Owner appointed
- ❑ Investigated
- ❑ Rout cause identified
- ❑ Correction and/or corrective action implemented

### RECALLS

- ❑ Triggers include:
  - Complaints
  - Rapid alert notifications
  - Inter Agency Collaborations
- ❑ Handled via CICA
- ❑ Participate in mock Recalls

# QUALITY MANAGEMENT

## PHARMACOVIGILANCE

*WHO DEFINITION*

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem*

*UNICEF ROLE*

As a wholesaler UNICEF plays the role of a *FACILITATOR ONLY*

*i.e.*

UNICEF pass any info received from the source (patient/country office) to the manufacturer (or our supplier, if different from the manufacturer)

**Ref:* https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

# UNICEF Quality Assurance Centre
## Supplier & Manufacturer Quality Management

unicef | for every child

## ONGOING ENGAGEMENT

- TRANSPARENCY
- QUALITY, SAFETY, EFFICACY
- UPDATED MANUFACTURING LICENSE & GMP CERTIFICATE
- HONOUR CONTRACTUAL AGREEMENTS
- VENDOR MANAGEMENT
- UNIQUE BATCH NUMBERS
- APPROVED API SUPPLIERS
- CoA's SHARED ON TIME
- INFORM UNICEF OF ANY MAJOR CHANGES *incl.* ALL GMDP NON-COMPLIANCES
- UNICEF GUIDELINES
- SUPPLIES FROM UNICEF APPROVED SITES


Thank you