Quality Assurance throughout the Supply Chain

Nutrition Supplier Forum
Copenhagen, 5th November, 2019
Quality Assurance in UNICEF

UNICEF applies the highest *international standards and regulatory frameworks* of safety and *compliance* to all the products/services we procure and deliver to the field.

UNICEF quality policy:
• commitment by all staff members, who strive to increase customer satisfaction.
• ensure that customers receive products and services which comply with the relevant quality, safety and regulatory requirements;
• maintain open and effective communications with our customers, suppliers and stakeholders, resolve issues/concerns quickly and effectively and ensure the satisfaction of all interested parties;
• build confidence and strong relationships in our Supply Chain Community as a leader and knowledge centre in regard to essential commodities for children;
• maintain efficient processes and systems that ensure cost effective procurement of products and services;
• commit to the continual improvement of systems and processes; and
• communicate this policy to all staff members and subject it to periodic review.

*The Quality Assurance Centre (QAC)*, based in SD, supports the procurement process by setting *quality standards* across the supply chain.
Quality Assurance in UNICEF. Policy Framework

UNICEF Objectives

Financial Rules and Regulations

Other UNICEF Policies

Programme Policy and Procedure Manual

Food Safety Policy

Supply Division Quality Management System:
Quality Policy - Quality Manual

Supply Manual
Procurement Guidelines & Procedures for other offices

Divisional Procedures
Supply Division’s Standard Operating Procedures

Country Offices

Supply Division
DIVISION OF ROLES AND RESPONSIBILITIES

**Procurement and technical**
- Specification development, product approval, product innovation and improvement, procurement

**Normative (Quality Assurance Center)**
- Manufacturer validation (including GMP inspections, predelivery inspections and product testing), complaints and recalls

**Other Centers**
- Transport Center: freight, etc.
- Supply Chain Strengthening Center: country system strengthening, in-country distribution and delivery, etc.
- Warehouse: Good distribution practice (GDP) etc.
Desired Outcome: Quality products are available and used by the intended beneficiaries requires Quality Assurance throughout the Supply Chain.
Quality Assurance Centre
Goals and Objectives

• QAC contributes to the realisation of UNICEF’s mission and supports the procurement process by setting and ensuring quality standards across the supply chain

• QAC promotes:
  • a proactive feedback system on both products and work processes in Supply Division
  • the efficiency and effectiveness of SD processes and ensures that products and services meet customer and regulatory requirements through the established and coordinated system of controls
Quality Assurance Centre

Structure

Chief, QAC

Quality Management Unit:
Responsible for ensuring that an effective and efficient Quality Management System (QMS) is implemented and maintained in UNICEF SD.
- Documentation management system
- Complaints
- Corrective actions
- Problem solving tools
- Quality matter related training
- Internal assessment/CA spot checking

Supplier Evaluation Unit:
Responsible for various elements surrounding vendor management, vendor evaluation (ethical and financial), UNGM vendor registration, receipt and registration of bids, supplier performance monitoring etc.
- Bids management
- Vendor evaluation (ethical and financial)
- UNGM vendor registration
- Vendor Review Committee

Quality Inspection Unit - Non Pharma:
Responsible for all inspections and evaluations carried out for non-pharmaceutical goods and services procured by UNICEF Supply Division (SD).
- Site inspection
- Goods receipt inspection
- Pre delivery inspection and supervision of loading
- Post delivery inspection
- Sample evaluations

Quality Inspection Unit - Pharma:
Responsible for various elements of the UNICEF Quality Assurance System for pharmaceuticals and nutritional products.
- GMP evaluations
- GDP self-inspection
- GDP training
- Quality control
- Goods receipt inspection
- Recalls management
- Import and export authorizations for narcotic and psychotropic substances
Quality Assurance Centre

Structure

Quality Management Unit
Tiziana Mazzoccoli
Lisa Kavli
Fariba Mousavian

Supplier Evaluation Unit
Ibaa Talo (OIC)
Jette Christiansen
Jenny Fang Hu
Evis Gusmari
Hellen Maina

Quality Inspection Unit - Non Pharma
Stuart Turner
Maria Beade
Aileen Selorio
John Pigou

Quality Inspection Unit - Pharma
Peter S. Jakobsen
Kasra Ghasemi
Unine Felix
Julie Zhu
Nicoletta Toth
UNICEF SD implements and maintains an effective and efficient Quality Management System (QMS), based on the Plan-Do-Check-Act (PDCA) process approach:

QAC supports the implementation of the QMS by implementing the continuous improvement process through:

- Documentation management system
- Complaints management system
- Corrective actions tracking
- Problem solving tools and training
- Internal assessment/CA spot checking

SD’s QMS is established in compliance with the UN and UNICEF Rules and Regulations, and the following standards:

- ISO 9001 Quality management systems - Requirements
- ISO 13485 Medical devices, ISO 22000:2018 Food Safety
- Codex Alimentarius FAO-WHO, WHO GDP and GMP standards.
Supplier Registration and Evaluation

Upholding high ethical standards and protecting UNICEF

Registration via United Nations Global Marketplace (UNGM)

Registration with UNICEF Global Services Centre (GSSC)

Supplier evaluation

General Terms and Conditions

• UN Supplier Code of Conduct

• Financial, Legal, Ethical

• UNICEF Policy Prohibiting and Combatting Fraud and Corruption
• Child Labour (CRC)
• Mines
• Prevention of sexual exploitation or abuse
• Policy on Conduct Promoting the Protection and Safeguarding of Children

ZERO Tolerance for unethical behaviour on the market

Handling allegations of supplier proscribed practices

VRC (Vendor Review Committee) sanctioning vendors for proscribed practices
UNICEF Quality Assurance system: Medicines and Nutrition

- Documentation system in place
  - Quality manual
  - Division procedures
  - Centre procedures
  - Supply Manual

- WHO “Model Quality Assurance System for Procurement Agencies MQAS” - TRS 986 Annex 3 is used as a model for procurement of both nutrition as well as pharmaceutical products

- PIC/S principles on Quality System Requirements for GMP Inspectorates is used as a guidance for planning and performing GMP inspections

- Nutrition manufacturers need to comply with ISO 22000 (plus Codex Alimentarius for Low Moisture Foods as applicable)

- All procurement activities are centralized in UNICEF Supply Division (procurement by UNICEF country offices requires authorization)

- QA system applies to all products and all vendors
UNICEF Quality Assurance system: Non-Pharma

• Documentation system in place
  - Quality manual
  - Division procedures
  - Centre procedures
  - Supply Manual

• Manufacturer audits and validation: trained QMS auditors

• Quality Control
  • Management of Pre-delivery inspections (PDI)
  • Sampling and Testing
  • Goods Receipt

• 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
Every entity that takes part in the UNICEF supply processes, services and operations (staff from HQs and Country Offices, clients, partners, suppliers, donors, etc,) can raise a complaint.

As a general guidance, an issue should be raised as a complaint in any of the following cases:

- related to a **product/service** delivered by SD
- related to an issue affecting SD **procurement process in every stage**;
- related to an **adverse effect** of pharmaceuticals and/or vaccines;
- it can have a material impact on **UNICEF’s image**
THANK YOU