SUPPLIER SUMMIT

USAID Global Health Supply Chain Program Supplier Summit
February 21-23, 2017
QUALITY ASSURANCE FOR
REPRODUCTIVE HEALTH COMMODITIES,
CONDOMS, AND PERSONAL
LUBRICANTS
GLOBAL HEALTH SUPPLY CHAIN –
QUALITY ASSURANCE (GHSC-QA) PROJECT
## USAID Global Health Supply Chain Program

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GHSC-QA PROJECT MANAGEMENT TEAM

Chryste Best
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Aida Cancel, PhD
Associate Director, Regulatory

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Associate Director, Business Operations

David Jenkins, PhD
Associate Director, Research

Thomas Layloff, PhD
Senior Technical Advisor

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Associate Director, Laboratory Testing

Steve Hamel
Director
Establish and implement a comprehensive Quality Assurance Program for USAID that:

- Provides global technical leadership regarding quality issues to the international quality assurance community
- Provides technical assistance to host country governments and other stakeholders
- Assures that health commodities purchased on behalf of USAID meet applicable quality standards
- Implements Model Quality Assurance System (MQAS) guidance (WHO Technical Report Series)
- Employs risk management practices to maintain diligence and recognizes that by limiting the risk of accepting products of inadequate quality, increased protection of the client/patient and USAID is ensured.

GHSC-QA provides independent Quality Assurance for:

- Task Order 1-HIV
- HIV RTKs (RMI)
- Task Order 3-Reproductive Health
- Task Order 4-Maternal and Child Health
**GHSC-QA ACTIVITIES AND OBJECTIVES**

**Quality Assurance**
- Product reviews (Product Questionnaire/Technical Information)
- Eligible/Approved supplier and product list
- Technical requirements and specifications for EOI{s, RFQs, and RFPs}
- Manage product complaints and incidents (including monitoring regulatory warnings)
- Product recall management
- Quality technical assistance
- Audits/CAPAs
- Statistical trending (CpK)
- Annual review and risk management

**Quality Control**
- Sampling
- Product testing
- Test method/transfer
- New technologies

**Technical Assistance and Leadership**
- NDRA training
- Laboratory capacity building
- Tanzania
- Afghanistan
- Côte d’Ivoire
- Uganda
- Zimbabwe
- Ethiopia
- Nigeria
- Ghana

**Global Collaboration**
- Donors
- WHO
- UNFPA
- UNICEF
- Global Fund
- Independent Advisory Groups
ELIGIBILITY AND GENERAL QUALITY ASSURANCE REQUIREMENTS
USAID (ADS 312) ELIGIBILITY OF COMMODITIES

<table>
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<th>Stringent Regulatory Authority (SRA)</th>
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<tr>
<td>• USAID recognizes the following:</td>
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<tr>
<td>• (a) the U.S. Food and Drug Administration, the Japanese Ministry of Health, Labor, and Welfare and the European Agency for the Evaluation of Medicinal Products (EMEA) centralized procedure;</td>
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<td>• (b) SwissMedic or Health Canada</td>
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<tr>
<td>• (c) European Union member states admitted prior to 1996 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom).</td>
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<th>WHO Pre-qualification</th>
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<tr>
<td>• WHO ERP 1 or 2 considered only in special cases</td>
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<th>Approved USAID Wholesalers</th>
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<tr>
<td>• Approved by GHSC-QA to provide essential medicines, laboratory supplies and medical equipment</td>
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<th>Other</th>
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<td>• Pharmaceuticals that do not qualify under any of the above categories</td>
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<tr>
<td>• Require additional quality information</td>
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<tr>
<td>• Assessment conducted by GHSC-QA based on risk analysis</td>
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<tr>
<td>• Additional quality testing by independent accredited laboratory</td>
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Eligibility Requirements

- Based on procurement needs
- No available SRA or WHO-PQ source
- Limited or no availability from approved wholesalers (e.g., long lead time, lack of country registration)
- Quality approved, locally registered sources

Quality Assurance Activities

- GHSC-QA assessment upon USAID request

THE GHSC-QA ASSESSMENT

Pharmaceutical Technical Questionnaire

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The product assessment is a comprehensive evaluation of the product and manufacturer.
PRODUCT/MANUFACTURER CHANGES: MAJOR VARIATIONS MUST BE COMMUNICATED TO GHSC-QA

Applies To

• Products approved for direct procurement
• Documentation required: Refer to Annex 3: WHO guidelines on variations to a prequalified product for pharmaceutical variations

Example of Major Variations

• Replacement or addition of a new manufacturing site or manufacturer
• Changes in the composition, manufacturing process, or lot size
• Changes in the standard claimed, specifications, or analytical procedures
• Changes in the immediate packaging (primary and functional secondary components) for the storage and shipment
• Change to an administration or measuring device
• Changes in the labelled storage conditions, shelf-life, or the in-use period
QUALITY ASSURANCE FOR REPRODUCTIVE HEALTH COMMODITIES
REPRODUCTIVE HEALTH COMMODITIES

- Oral contraceptives
- Emergency contraceptives
- Injectable contraceptives
- Contraceptive implants
- Intrauterine devices (IUD TCu380A)
- Cyclebeads
REPRODUCTIVE HEALTH PHARMACEUTICALS

Eligibility Requirements

- SRA
- WHO prequalification
- GHSC-QA process
  - GHSC-QA technical evaluation required
  - Abbreviated for SRA and WHO PQ products

QA and QC Activities

- CoA review required for each lot
- Pre-shipment, concurrent, or post-shipment testing depending on risk assessment
- Compliant cGMP audits
  - Frequency dependent on regulatory status and history
- Report cards
- Review of manufacturers’ quality metrics
Eligibility Requirements

- SRA
- WHO/UNFPA prequalification
- ISO 9001, 13485, 14000 manufacturer
- CE Mark
- GHSC QA technical evaluation required

QA and QC Activities

- Frequency of GHSC-QA audits dependent on risk assessment (2 – 3 years)
- CoA review required for each lot
- Pre-shipment, concurrent or post-shipment testing
QUALITY ASSURANCE FOR MALE CONDOMS, FEMALE CONDOMS, AND PERSONAL LUBRICANTS
MALE CONDOMS

Eligibility Requirements
• Condoms must have a U.S. FDA 510(k) for plain, parallel-straight walled, 49 and 53mm.
• Color and scented condoms must have specific 510(k)
• ISO Certified to 9001, 13485, 14000
• WHO/UNFPA pre-qualified list
• EU CE mark
• GMP-registered facility
• Monitor proteins, nitrosamines, and residual accelerators

QA and QC Activities
• Pre-shipment testing to ISO 4074
• Frequency of GHSC-QA audits dependent on risk assessment (2 – 3 years)
• 180-day accelerated stability studies
• Odor evaluation
• Annual testing of proteins, nitrosamines, residual accelerators
• Trending of manufacturer’s data
FEMALE CONDOMS

Eligibility Requirements

• U.S. FDA 510 (k)
• EU CE Mark
• UNFPA Pre-qualified List – referenced
• GMP-registered Facility
• ISO Certified to 9001, 13485, 14000
• GHSC-QA Medical Device Product Assessment Required

QA and QC activities

• Pre-shipment testing
• GHSC-QA audits frequency dependent on risk assessment (2 – 3 years)
PERSONAL WATER-BASED LUBRICANTS

Eligibility Requirements

• U.S. FDA 510K
• Compliance with WHO/UNFPA/FHI360 Advisory Note (i.e., water-based, osmolality < 1200 mOsm/kg, pH 5.5 – 7, avoid polyquarternary compounds)
• EU CE Mark
• GMP-registered Facility
• ISO Certified to 9001, 13485, 14000
• GHSC-QA Medical Device Product Assessment required
• Presentation: Sachet

QA and QC Activities

• Frequency of GHSC-QA audits dependent on risk assessment (2 – 3 years)
• Pre-shipment or concurrent testing dependent on risk assessment
RESOURCES

• USAID Automated Directives System (ADS) Chapter 312: Eligibility of Commodities

• USAID ADS 312 Additional Help Document: Pharmaceuticals and Medical Supplies


• US Food and Drug Administration (US FDA)

• Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360
QUALITY ASSURANCE FOR MATERNAL NEWBORN AND CHILD HEALTH COMMODITIES (TO4)
MATERNAL, NEWBORN AND CHILD HEALTH COMMODITIES

- 4% Chlorhexidine Gel [7.1% chlorhexidine digluconate for umbilical cord care]
- Magnesium Sulphate injection (0.5 g/mL) - 2 mL
- Oxytocin 10 i.u. injectable
- Misoprostol 200 microgram tablet
- Zinc Sulphate injection
- Amoxicillin (40 mg/ml, 1mL or 2 mL ampoule)
- Gentamicin (20 mg/mL, 2 mL ampoule)
- Oral Rehydration Salts (20.5 g sachet)
- Zinc tablets (20 mg)
- Dexamethasone injectable
- Neonatal Resuscitation Device (Neonatal Bag, Mask Resuscitator, Suction Device, Training Model)
MNCH PHARMACEUTICALS (ESSENTIAL MEDICINES)

Eligibility requirements

- SRA
- WHO prequalification
- Approved USAID wholesalers
- GHSC-QA Process
  - GHSC-QA technical evaluation required
  - Abbreviated for SRA and WHO PQ products
  - Full review for non-SRA, non-WHO-PQ

QA and QC activities

- Compliant cGMP and QMS audits
  - Frequency dependent on regulatory status
  - International wholesaler audits
  - CoA review required for each lot
  - Pre-shipment, concurrent, or post-shipment testing depending on risk assessment
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The USAID Global Health Supply Chain-Quality Assurance project provides quality assurance and quality control services. We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, maternal and child health, and population and reproductive health commodities.