SUPPLIER SUMMIT

USAID Global Health Supply Chain Program Supplier Summit
February 21-23, 2017

SUPPLIER SUMMIT

USAID Global Health Supply Chain Program

QUALITY ASSURANCE FOR REPRODUCTIVE HEALTH COMMODITIES, CONDOMS, AND PERSONAL LUBRICANTS

USAID FROM THE AMERICAN PEOPLE

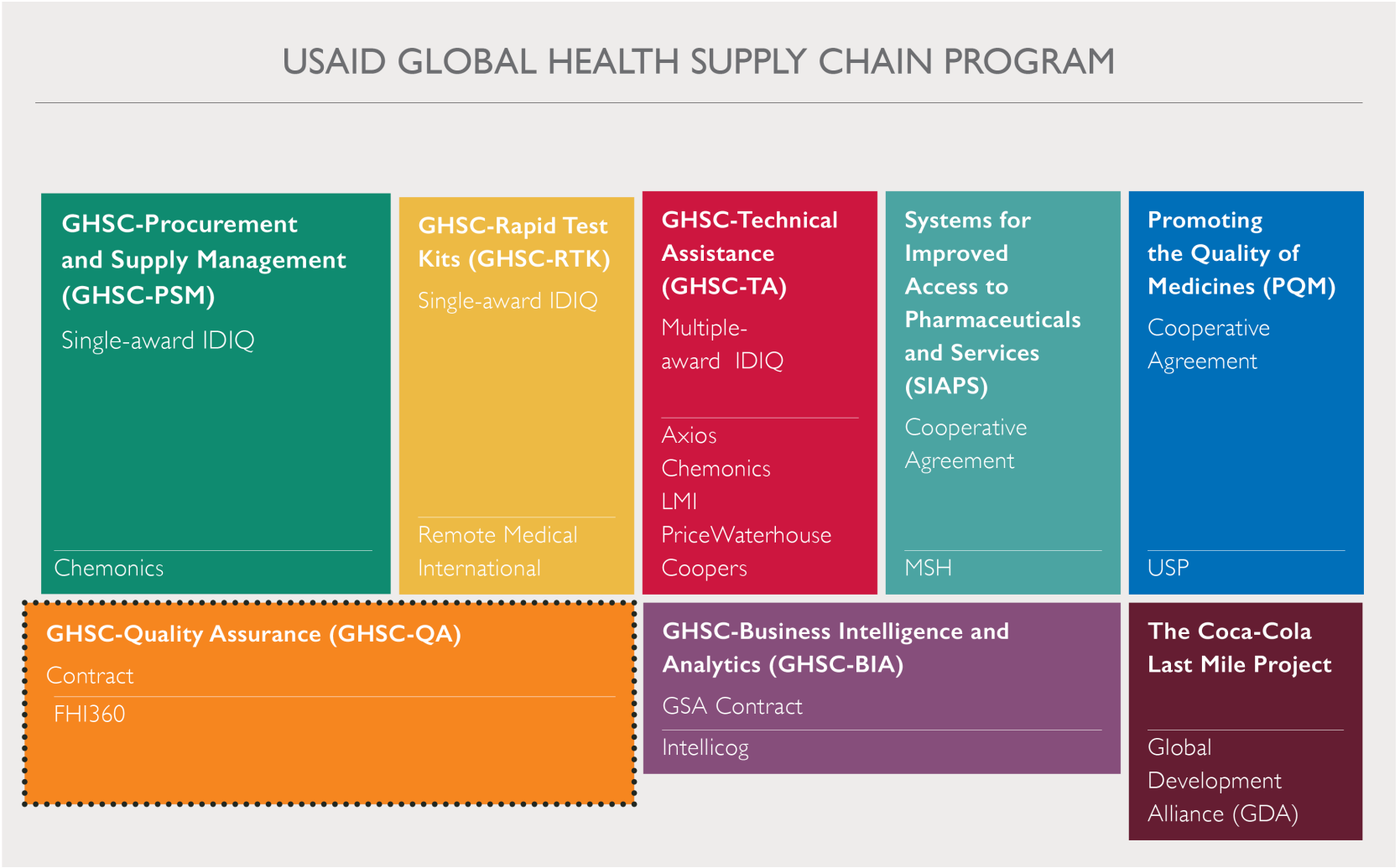
PEPFAR U.S. President's Emergency Plan for AIDS Relief

USAID FROM THE AMERICAN PEOPLE CDC

U.S. President's Malaria Initiative

GLOBAL HEALTH SUPPLY CHAIN – QUALITY ASSURANCE (GHSC-QA) PROJECT

GENERATION NEXT



GHSC-QA PROJECT MANAGEMENT TEAM

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GHSC-QA

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

Objectives

- Quality Assurance
- Quality Control
- Technical Assistance and Leadership
- Global Collaboration

GHSC-QA ACTIVITIES AND OBJECTIVES

Quality Assurance

- Product reviews (Product Questionnaire/Technical Information)
- Eligible/Approved supplier and product list
- Technical requirements and specifications for EOIs, 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

Stringent Regulatory Authority (SRA)

- USAID recognizes the following:
  - (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;
  - b) SwissMedic or Health Canada
  - (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).

WHO Pre qualification

- WHO ERP 1 or 2 considered only in special cases

Approved USAID Wholesalers

- Approved by GHSC-QA to provide essential medicines, laboratory supplies and medical equipment

Other

- Pharmaceuticals that do not qualify under any of the above categories
- Require additional quality information
- Assessment conducted by GHSC-QA based on risk analysis
- Additional quality testing by independent accredited laboratory

THE GHSC-QA ASSESSMENT

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

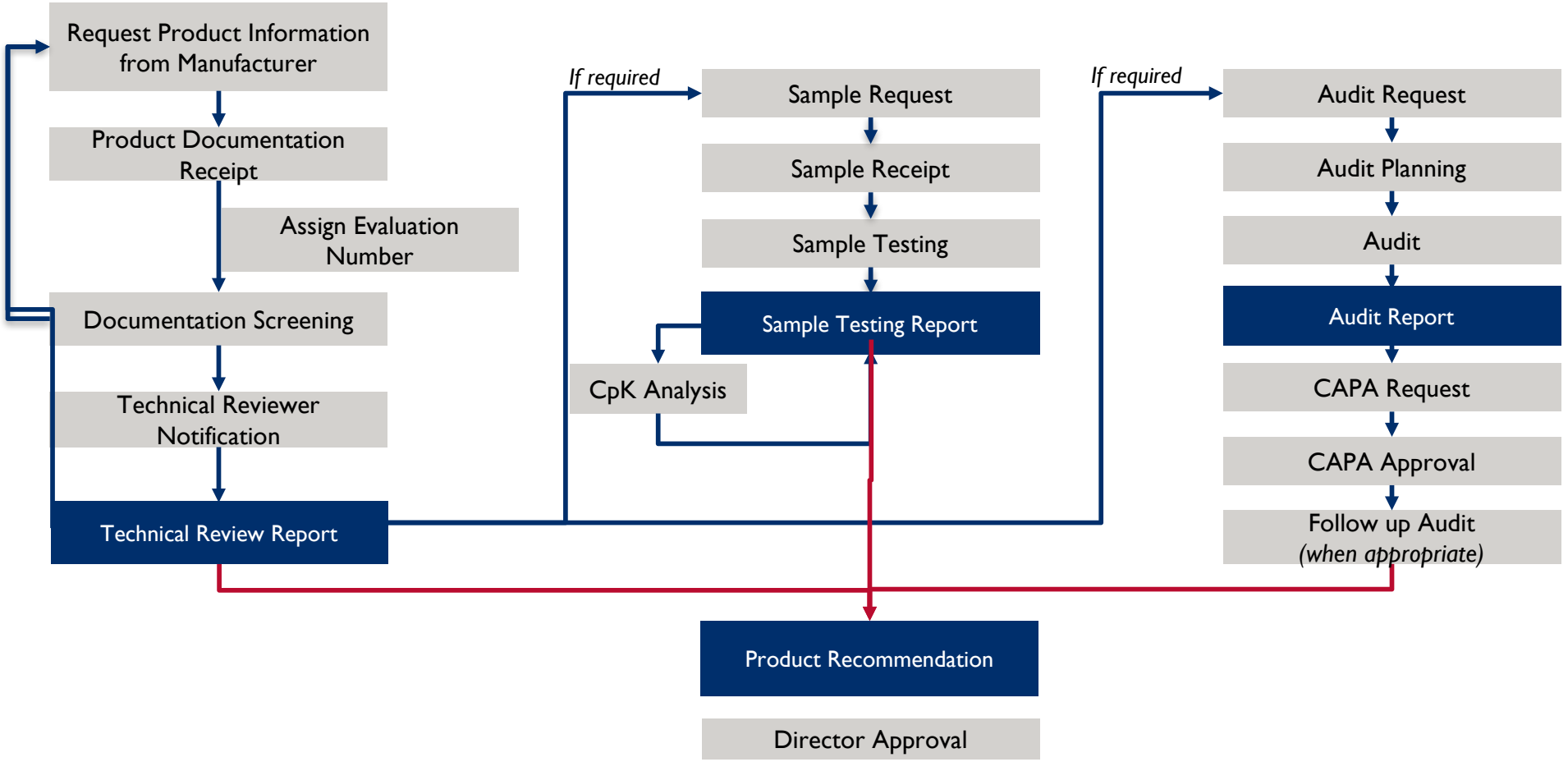
Quality Assurance Activities

- GHSC-QA assessment upon USAID request.

Pharmaceutical Technical Questionnaire

PRODUCT ASSESSMENT (APPROVAL PROCESS)

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
  http://apps.who.int/prequal/info_general/documents/TRS981/TRS981_annex3.pdf

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

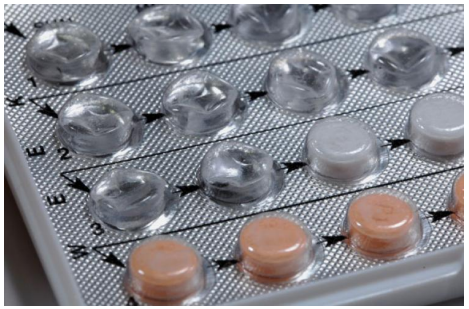
- Oral contraceptives
- Emergency contraceptives
- Injectable contraceptives
- Contraceptive implants
- Intrauterine devices (IUD TCu380A)
- Cyclebeads

REPRODUCTIVE HEALTH PHARMACEUTICALS

- Oral Contraceptives
- Emergency Contraceptives
- Injectable Contraceptives
- Contraceptive Implants

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

REPRODUCTIVE HEALTH MEDICAL DEVICES

IUD Tc8380 A

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 mOm/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

RESOURCES

- USAID Automated Directives System (ADS) Chapter 312: Eligibility of Commodities
- USAID ADS 312 Additional Help Document: Pharmaceuticals and Medical Supplies
- Model Quality Assurance System for Procurement Agencies. WHO Technical Report Series, No. 986, 2014, Annex 3 (2014; 72 pages)
- US Food and Drug Administration (US FDA)
- Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360

APPENDIX

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.