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 HIV/AIDS COMMODITIES AND ESSENTIAL MEDICINES

USAID FROM THE AMERICAN PEOPLE

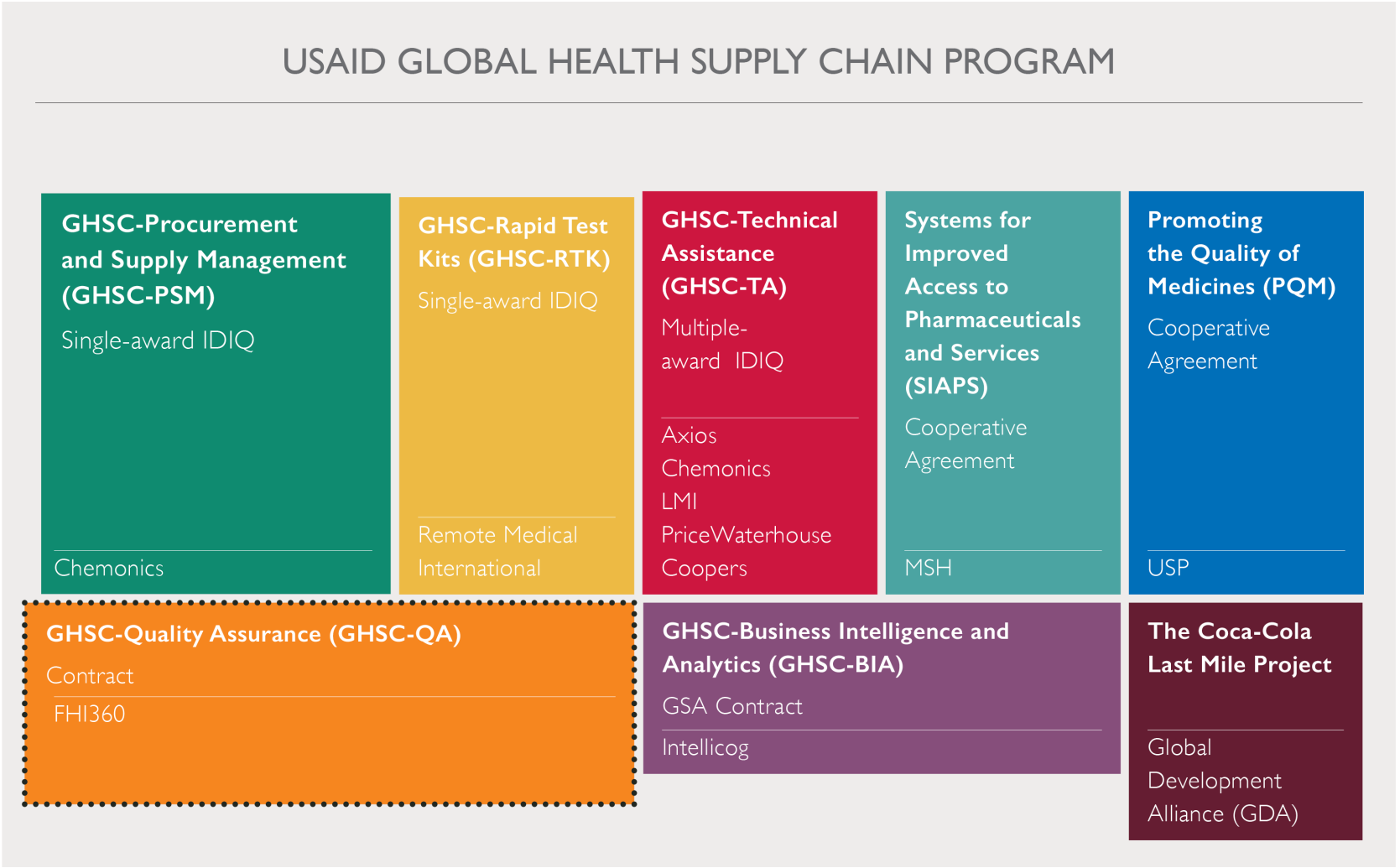
PEPFAR U.S. President's Emergency Plan for AIDS Relief

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

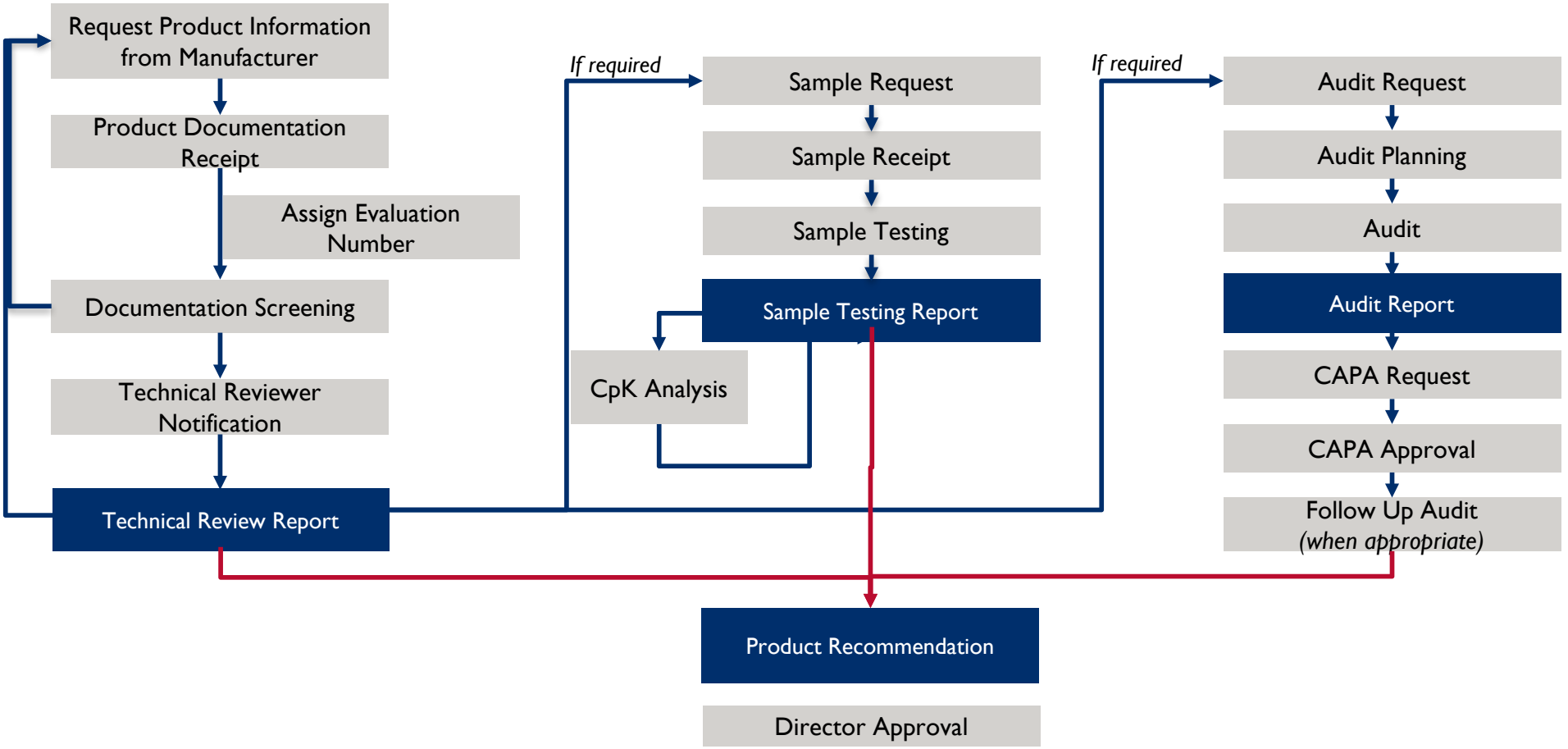
Pharmaceutical Technical Questionnaire

Other GHSC-QA Product Questionnaires for:

- Medical Devices
- RTKs
- Food by Prescription

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

Examples 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 labeled storage conditions, shelf-life, or the in-use period

QUALITY ASSURANCE FOR HIV/AIDS COMMODITIES AND ESSENTIAL MEDICINES

HIV/AIDS COMMODITIES

- Antiretrovirals (ARVs)
- Essential Medicines
- Food by Prescription
- HIV Rapid Test Kits
- Non-HIV Rapid Test Kits
- Laboratory Supplies
- Voluntary Medical Male Circumcision Kits
- Instrument-based Diagnostics

ANTIRETROVIRALS (ARVs)

Eligibility Requirements

- U.S FDA-approved products (NDA or ANDA)
- U.S. FDA tentatively approved products in the HIV/AIDS Drugs Authorized for Purchase under PEPFAR (http://www.fda.gov/internationalPrograms/PEPFAR/ucm119231.htm)
- Climatic zone; Preference to Zone IVb
- Storage conditions: Should be adequate for 30°C and high humidity

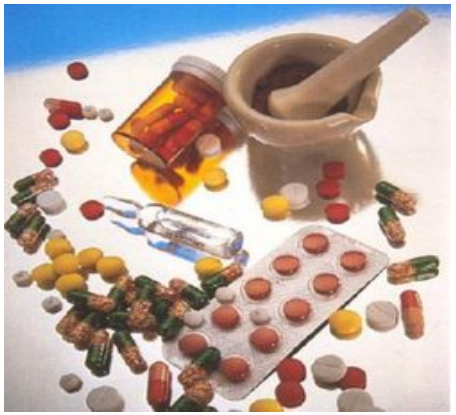
QA and QC Activities

- "For Cause" audits
- Certificate of Analysis required
- Annual product testing post shipment

ESSENTIAL MEDICINES (PHARMACEUTICALS)

Eligibility Requirements

- SRA
- WHO-PQ
- Approved USAID wholesalers
- Other - 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, QMS and/or MQAS audits
  - Frequency dependent on regulatory status and/or risk assessment
- CoA review required for each lot
- Pre-shipment, concurrent, or post-shipment testing depending on risk assessment

VOLUNTARY MEDICAL MALE CIRCUMCISION KITS

- ❑ MC kit for all surgical procedures, Single use, Sterile
- ❑ MC kit, additional instruments for Dorsal Slit/Sleeve Resection, Single Use, Sterile
- ❑ MC kit, Essential Consumables Pack, Single Use, Sterile
- ❑ MC kit, Forceps Guided Procedure, Single Use, Sterile
- ❑ MC kit, Reusable Instruments for Dorsal Slit/Sleeve Resection, Non-Sterile
- ❑ MC kit, Reusable Instruments for Forceps Guided Procedure, Non-Sterile
- ❑ MC1:C25C kit for all surgical procedures , Single use, Sterile, 1kit
- ❑ PrePex Removal Kit

Eligibility Requirements

- Voluntary Medical Male Circumcision Technical Working Group (VMMC TWG) determines requirements and technical specifications for each type of kit.
  - Supplier must meet
    - ISO13485:2016; and
    - ISO 11135-1:2007 (for sterile kits)
  - GHSC-QA audit
  - Validation of sterilization cycles for the various kit options

QA and QC Activities

- Frequency of GHSC-QA audits dependent on risk assessment (2 – 4 years)
- Pre-shipment, concurrent, or post-shipment sterility testing dependent on risk assessment and physical inspection.
- Sterility validation data reviewed and approved by GHSC-QA

FOOD BY PRESCRIPTION

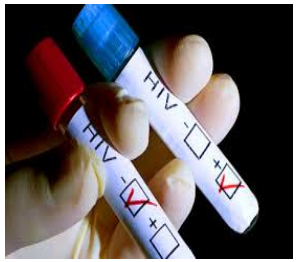
Eligibility Requirements

- USDA, MSF, UNICEF or GHSC-QA Audit
- Compliance with USAID Commodity Specification:
  - RUF Ready-to-Use Nutritional Food for Use in International Food Assistance Programs (Dec 21, 2015)
  - Fortified Blended Flour (TBD)
- GHSC-QA FBP Product Assessment is required.
- GAIN premix suppliers

QA and QC Activities

- Frequency of GHSC-QA audits dependent on risk assessment (2 – 4 years)
- Pre-shipment, concurrent, or post-shipment testing

HIV AND NON-HIV RAPID TEST KITS



Eligibility Requirements

- US FDA or prequalification of a test kit by the World Health Organization (WHO) is the primary basis for technical approval.
- USAID reserves the right to require the test kit be evaluated by an independent laboratory.
- A WHO prequalified test kit must meet the GHSC-QA general technical documentation requirements. GHSC-QA In Vitro Diagnostic Product Assessment may be requested.

QA and QC Activities

- Frequency of GHSC-QA audits dependent on risk assessment (2 – 4 years)
- Pre-shipment, concurrent, post-shipment testing dependent on risk assessment

INSTRUMENT-BASED DIAGNOSTICS

Eligibility Requirements

- Prequalification by the World Health Organization (WHO) is the primary basis for technical approval.

QA and QC Activities

- TBD

LABORATORY SUPPLIERS

Eligibility Requirements

- Manufacturers sourced for these product categories must be quality assured with certifications like ISO 9001:2000 or ISO 13485 or ISO 13488 or EN 46001 or CE 01847, or approved by standards regulatory bodies in country of manufacturer, which bodies must be accredited by or affiliated to standards institutes like ISO, with copy of certification(s) attached.

QA and QC Activities

- Copy of the lot Certificate of Analysis duly signed by authorized persons for each product is to be provided.
- USAID reserves the right to require product to be evaluated by an independent laboratory.

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 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
- Frequency of GHSC-QA audits 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

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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.