



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 MALARIA COMMODITIES



USAID
FROM THE AMERICAN PEOPLE



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



USAID
FROM THE AMERICAN PEOPLE



U.S. President's Malaria Initiative

OUTLINE

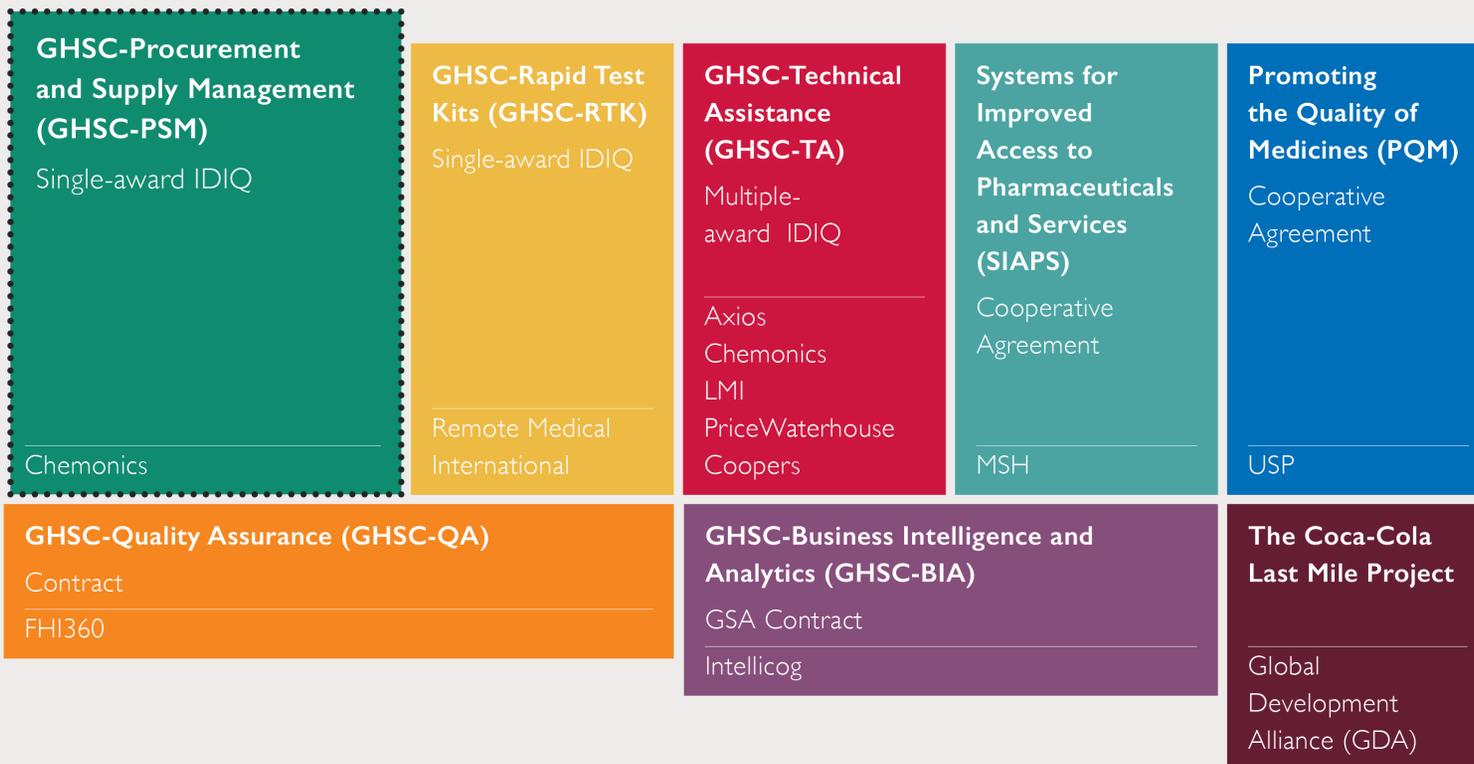
- Setting priorities
- Introductions
- What is the difference between GHSC-QA and GHSC-PSM QA?
- QA/QC requirements for malaria commodities
- Let's talk about priorities
- Q & A

WHAT QA INFORMATION DO YOU NEED TO DO BETTER BUSINESS WITH GHSC-PSM?

- A. Differences between GHSC-QA and GHSC-PSM QA
- B. Minimum requirements to participate in tenders
- C. Sampling and testing requirements
- D. Steps to speed up the process
- E. Contacts for malaria QA
- F. Other

WE'RE ONE OF EIGHT KEY PROJECTS

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM



GHSC-PSM QA: FOCUS ON **MALARIA**

GHSC-QA	GHSC-PSM QA
HIV/AIDS	Malaria
Population and Reproductive Health	
Maternal and Child Health	

Common Activities

- Establishing list of eligible products
- Establishing QC requirements
- Conducting inspections, sampling, and testing
- Performing product incident investigations
- Managing product recalls
- Auditing suppliers

GHSC-PSM IS ALSO RESPONSIBLE FOR GDP COMPLIANCE FOR ALL COMMODITIES IT PROCURES

- Ensures GDP compliance with freight forwarders & regional warehouses
- Assists GHSC-PSM Country Programs in operating GDP-compliant supply chains
- Logistics related to recall and/or quarantine

PMI RATIONALE FOR IN-HOUSE QA

Inherent Characteristics of Malaria Confer Unique Commodity Requirements

- Vector-borne
- Relatively quickly changing epidemiology
- Reliance on vegetal API
- Disease pathology and acute nature

Therefore, Requires Unique Contractual Requirements

- In-house QA/QC affords contractual flexibility
- Success of PMI from 2005-2015 in part due to availability of commodities when/where needed

MALARIA QA ROLE IN THE PROCUREMENT PROCESS

Establish List of Preferred Suppliers

- Clear eligibility criteria
- Recommendation based on evaluation of proposals with respect to meeting and exceeding quality requirements

Establish Quality Terms and Conditions Included in RFX Events

- Detailed description of QA/QC requirements

Execute QC Requirements as Outlined in Terms and Conditions

- Commodity-specific

MINIMUM REQUIREMENTS TO PARTICIPATE AND BE ELIGIBLE

Commodity	Eligibility Requirements
Antimalarial medicines	SRA ¹
	WHO PQ
	USAID pre-approved wholesaler
RDTs ²	P.falciparum panel detection score of at least 75% at 200 parasites μ l
	P.vivax, panel detection score of at least 75% at 200 parasites μ l
	False-positive rate should be less than 10%
	Invalid rate should be less than 5%
LLINs ³	WHOPES Phase II

1:As per ADS 312: <https://www.usaid.gov/sites/default/files/documents/1864/ADS312AdditionalHelpDocument.pdf>

2:As per WHO Information <http://www.who.int/malaria/publications/atoz/rdt-selection-criteria.pdf?ua=1>

3:As per PMI Memorandum: https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/itn_procurement_specifications.pdf?sfvrsn=4

CURRENT CONTRACTUAL MECHANISMS FOR MALARIA

Commodity	List of Preferred Vendors
Alu	IDIQ with select vendors in place until Feb 2018
ASAQ	IDIQ under evaluation (12 month awards)
Other antimalarial medicines	Spot buys from USAID pre-approved wholesalers
LLINs	Select vendors as results of EOI until July 2017
RDTs	IDIQ under evaluation (12-month awards)

FREQUENCY OF INSPECTION, SAMPLING, AND TESTING

Commodity	Category	QC Requirement
Antimalarial medicines	SRA ¹	Each batch: Document review
	WHO PQ	Subset of batches: Annual testing ² Each batch: Pre-shipment or concurrent ³
	USAID pre-approved wholesaler	Each batch: Pre-shipment

1: As per ADS 312: <https://www.usaid.gov/sites/default/files/documents/1864/ADS312AdditionalHelpDocument.pdf>

2: Sampling and testing guided by ISO 2859-1; S2

3: After reaching compliant results for 10% of the annual production capacity all further batches → concurrent

FREQUENCY OF INSPECTION, SAMPLING AND TESTING (CONT.)

Category	QC Requirement
RDTs	Each batch: Pre-shipment
LLINs	Each batch: Concurrent

Under special circumstances, and with PMI guidance, eligibility criteria and QC requirements may be adjusted

FOUR KEY STEPS IN THE QA PROCESS

1. Supplier Communicates Goods Are Ready

- Provide packing list, invoice, and CoAs to GHSC-PSM QA
- Sampling/inspection location and point of contact

2. GHSC-PSM Executes Sampling and Inspection

- SGS representative will inspect and sample goods and ship to testing lab

3. Qualified Labs Test Samples

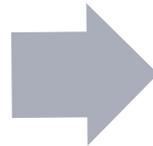
- Antimalarials:
 - India (SGS-Chennai & Stabicon) or Europe (SGS-Belgium & Proxy)
- RDTs: WHO/FIND labs (IPC-Cambodia or RITM-Philippines)
- LLINs: FHI 360 (USA)

4. GHSC-PSM QA Makes Final Determination

CURRENT STATE VS. FUTURE FOCUS

Antimalarials

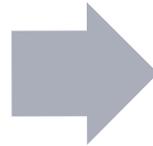
QC lab network established
Performing method transfers
(if applicable)
Assigning products to network



Drive efficiencies in testing
turnaround time

LLINs

One lab
Challenges with efficient pick-up

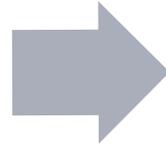


Expand network to multiple labs

CURRENT STATE VS. FUTURE FOCUS

RDTs

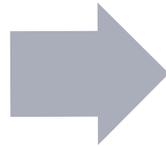
WHO/Find assigns lab



Monitor global landscape

Management

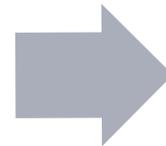
Developing metrics



Monitor metrics & implement CAPAs when applicable

Global Engagement

Exploring areas of mutual interest with WHO PQ & other donors



Contribute to global malaria QA community

ACTIONS YOU CAN TAKE TO SPEED UP THE PROCESS

- A. Provide pack list, CoAs, sampling location, and contact promptly
- B. Fill order with minimum number of batches possible
- C. Clear communications
- D. Provide feedback for continuous improvement

LET'S HEAR FROM YOU

<https://api.cvent.com/polling/v1/api/polls/sp-dhx515>

QUESTIONS?



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The USAID Global Health Supply Chain-Procurement and Supply Management project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security.

We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, maternal and child health, and population and reproductive health commodities.