

Global Drug Facility Super Team Meeting: Supply Stakeholders' Meeting for Second-line anti-TB drugs

Rio de Janeiro, Brazil
March 17-20, 2009

Trip Report

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About USP DQI

The United States Pharmacopeia Drug Quality and Information (USP DQI) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00017-00), provides technical leadership to more than 30 developing countries to strengthen their drug quality assurance programs, ensure the quality of medicines and promote public health.

USP DQI helps build local, national and regional capacity to improve the standards of drug manufacturing and distribution, reduce the impact of infectious diseases, mitigate the effects of the HIV/AIDS epidemic, and advance the appropriate use of medicines. This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to USP DQI.

Abstract

The director of USP DQI attended the Global Drug Facility (GDF) Super Team meeting and presented on the service USP DQI provides to manufacturers to help them prepare registration dossiers for second-line anti-tuberculosis (TB) drugs for the consideration of the WHO prequalification program. At the request of the TB team at USAID/Washington, USP DQI has collaborated with GDF and the prequalification program to assist manufacturers in dossier preparation and facilitate the submission of high quality dossiers. Under this arrangement, USP DQI will obtain a list of priority second-line anti-TB drugs from GDF and will initiate contact with manufacturers with the view to provide technical assistance in preparing registration dossiers followed by an on-site GMP assessment in preparation for WHO audit inspection. This was the first meeting with TB stakeholders to showcase this service.

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Key Words

Global Drug Facility, Global Fund, Second-line anti-TB medicines, WHO, Prequalification program, GMP Compliance.

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I would like to express appreciation to the USP DQI administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.

Finally, I would like to thank the USAID/Washington TB team, in particular Susan Bacheller and Irene Koek, for their continued support and leadership. I would also like to thank Anthony Boni and Veerle Coignez at USAID/Washington for their guidance and support of the USP DQI program.

ACRONYMS

API	Active Pharmaceutical Ingredient
CTO	Cognizant Technical Officer
EoI	Expression of Interest
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GMP	Good Manufacturing Practices
MSH/SPS	Management Sciences for Health/Strengthening Pharmaceutical Systems
PICs	Pharmaceutical Inspection Cooperation Scheme
SDRA	Stringent Drug Regulatory Authority
TB	Tuberculosis
TRP	Technical Review Panel
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
WHO	World Health Organization

Background

As the implementing mechanism for USAID to strengthen drug quality assurance systems in developing countries, USP DQI has provided support to the Health TB team at USAID/Washington in the following areas:

- Technical leadership in drug quality related to first- and second-line anti-TB medicines
- Support global initiatives, such as STOP TB, in particular the Global Drug Facility's effort to provide quality assured anti-TB medicines
 - Provide technical assistance to manufacturers to facilitate the prequalification of second-line anti-TB medicines.
- Review technical literature and provide comments as guidance and recommendations to the Health TB team.
- Work with USP's Documentary Standards Division to develop monographs for first- and second-line anti-TB medicines.

In the area of support to global initiatives, USP DQI has been working closely with GDF to increase the number of prequalified second line anti-TB medicines. In this regard, USP DQI has collaborated with the WHO prequalification team and GDF to provide technical assistance to manufacturers in dossier preparation and also provides on Good Manufacturing Practices (GMP) assessment audits of manufacturers to prepare them for WHO prequalification. The super team meeting in Rio provided an opportunity for USP DQI to showcase these services.

In the past, few anti-TB drug manufacturers expressed interest in participating in the prequalification program, probably due to a lack of understanding of the process. The quality of the dossiers that were submitted was questionable, leading to delays in prequalification.

In 2008, USP DQI collaborated with GDF to develop criteria for GMP inspections of manufacturers by WHO, subsequently leading to product approval for procurement by GDF. Three manufacturers responded, and the quality of dossiers submitted was questionable. The USAID-TB CTO approached USP DQI and advised getting involved earlier in the prequalification process. It was agreed that USP DQI would assist manufacturers to prepare dossiers, review the dossiers for GMP compliance, and conduct assessments of their facilities in order to identify gaps and make recommendations for compliance with international GMP standards.

A detailed description of the services provided and the scope of work with manufacturers can be found at: <http://www.usp.org/worldwide/dqi/WHOQualificationRequest.html>

GDF ensures access to high quality drugs at affordable prices for countries in need. Since 2001, GDF had provided anti-TB drugs to 95 countries, including 18 of the 22 countries bearing the highest TB burden. GDF offers the following services: e

- Grant service at no cost to poor countries that cannot afford to procure anti-TB medicines
- Procurement services to countries that have adequate financial resources, but a lack of expertise in procurement and pharmaceutical management. International Dispensary Association Foundation is the procurement agent for second-line anti-TB drugs and the

Deutsche Gesellschaft für Technische Zusammenarbeit is the procurement agent for first-line anti-TB drugs

- Technical assistance for in-country drug management and logistics
- Transitional grants for first-line anti-TB drugs for countries waiting for funds from donor agencies, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM)
- Emergency grants for countries facing stock outs
- Mandatory procurement through GDF for second-line anti-TB drugs using Global Fund money
- Strategic stockpile of first- and second-line anti-TB drugs to meet urgent short-term demand

Purpose of the Conference

The conference was organized by GDF to accomplish the following:

- Update partners on new initiatives at GDF and STOP TB secretariat to increase access to first- and second-line anti-TB medicines
- Engage manufacturers in discussions about forecast, quantification, and expected procurement plans for first- and second-line anti-TB drugs as well as address manufacturers' concerns about the procurement process
- Introduce existing and new partners and encourage networking between partners involved in increasing access to quality-assured anti-TB medicines

Source of Funding

Funding was provided through Core TB.

Summary of Meeting Proceedings

Global Drug Facility Presentation

GDF is an arm of the Stop TB partnership and has the mandate to increase access to quality assured anti-TB medicines at the lowest possible price. To date, GDF has provided medicines to 95 countries, including 18 of the 22 high burden countries. GDF is both a funding agency and procurement organization for anti-TB medicines and, more recently, has started to procure TB diagnostic equipments. Some information revealed at the meeting includes:

- Projected orders for anti-TB medicines in 2009 are \$33.8 million compared to \$16 million in 2008. In 2009, the largest GDF funds will be spent on procurement of Para-aminosalicylic acid (\$9.7 Million) followed by Capreomycin (\$5.8 Million)
- GDF is funded mainly by Global Fund, UNITAID, CIDA, and USAID
- Under the current GDF-UNITAID MDR-TB Initiative, GDF maintains a strategic rotating stockpile and revolving fund for emergency purchases for countries in need.
- Tenders for second-line anti-TB medicines were launched in September 2008 and awards will be issued in April 2009 with final contracts in place by July 2009.
- The tendering process at GDF is a two-stage process including technical and price criteria. Companies are filtered based on meeting technical requirements; selection is then made based on price. There were criticisms that this process gives the appearance that GDF uses price as the main criteria for the selection of vendors.

- Only three second-line anti-TB medicines are currently prequalified: Cyprofloxacin, Cycloserine (Macleod), and Ethionamide (Macleod). Cyprofloxacin was prequalified for HIV/AIDS opportunistic infection.
- The quality standards used by GDF are 1) product is prequalified; 2) product is approved by a stringent regulatory authority; and 3) product and site are found to be acceptable by a technical review panel (TRP) in an interim assessment review. To be eligible for TRP approval, a product must be manufactured at a GMP-approved site (approved by WHO, stringent drug regulatory authority (SDRA), or Pharmaceutical Inspection Cooperation Scheme (PICS)) and approval is pending by WHO or SDRA.

Challenges

- Registration is becoming a bottleneck for access to anti-TB medicines – it was noted at the meeting that there are delays in registration of anti-TB drugs leading to poor access.
- Poor country commitment to enroll patients – with new diagnostic tools, patient enrollment is predicted to increase significantly if a country is committed.
- Country commitment to expand local markets to international competition
- Need to strengthen national medicine regulatory authority for faster registration and oversight of drug quality
- Better forecasting needed
- Need to harmonize QA policies

These challenges will be discussed at the Beijing meeting (April 2009) following the GDF Super Team meeting.

Clinton Foundation Presentation

The Clinton Foundation - Drug Access team gave a presentation on their experiences in improving process and products in order to reduce costs for HIV/AIDS. The foundation is currently a working partner of UNITAID and collaborates in several ways to reduce costs for HIV/AIDS medicines. The main drivers in decreasing cost and increasing access include:

- Providing access to timely market information
- Broadening supply base and conduct pooled procurements
- Improving procurement practices
- Working with manufacturers to reduce input and risk costs, thereby lowering price.

An example given was the cost of the anti-HIV/AIDS drug Tenofovir Disoproxil Fumarate, reduced from \$2300 per kg in 2005 to less than \$700 per kg in 2009.

WHO Prequalification Program Presentation

Dr. Janos Pogany, a pharmacist and senior reviewer on the prequalification program, gave a presentation on the prequalification process and background of the program. The objective of the program is to build capacity of DRAs in developing countries and to assess the safety, efficacy, and quality of medicines. Participation in the prequalification program starts with a company responding to an Expression of Interest and submitting a dossier. The dossier is then assessed by a team at the Pharmaceutical Quality Information Forum in Copenhagen which convenes every two months. After a successful assessment of the dossier, inspection of the company's

manufacturing facility is scheduled. The inspection team usually comprises of a WHO employee, an expert, and a member of the country inspectorate. After a successful inspection, a prequalification letter is issued which specifies the site, batch size, retest period, active pharmaceutical ingredient (API), and finished dosage form specification reference number. Highlights of his presentation include:

- 36 dossiers are under review for prequalification, as of February 2009
- Review of drug product dossiers requires a review of the corresponding API drug master file, which contains information about the API, the process used to make it, and its quality and stability.
- The prequalification team does not approve the drug master file, they only accept it.
- Variations to approved product should be pre-approved and post-market monitoring is in the purview of the prequalification program

Challenges

- More clarity is needed on the requirements for prequalification. Manufacturers expressed concern that certain requirements are brought to their attention during assessment or inspection. Specifically, technology transfer requirements need clarification.
- Response time by manufacturers to queries and comments from prequalification is inadequate and needs to be improved. USP DQI will help with this with their new arrangement with GDF to help manufacturers prepare dossiers and respond to prequalification queries.
- Rapid turn-around time is needed for prequalification, from dossier submission to receiving WHO approval. UNITAID expressed concern that some companies were turning to SDR approval instead of prequalification with the hope of getting a waiver from WHO.
- Product specifications approved by WHO should be made available to procurement agencies so that they can cross check with those submitted by manufacturers for procurement purposes. Global Fund expressed concern that they have observed differences in specifications between what are prequalified and subsequent certificates of analyses from manufacturers.

USP DQI Presentation

The USP DQI director gave a presentation (full presentation can be found in **Annex 2**) on the services that USP DQI is providing to manufacturers of second-line anti-TB medicines to strengthen the quality of their dossiers and help prepare them for a successful site inspection by a prequalification team. The highlights of the presentation include:

- Background of the USP DQI program and other disease programs that they support
- USP DQI assisted a Capreomycin producer in India to prepare a dossier, which was accepted for review, and has conducted follow up visits to the company to help them address questions by the prequalification team.
- USP DQI provides assistance toward GMP compliance by also conducting site assessment audits to prepare companies for WHO inspection.
- USP DQI maintains a help desk to answer queries from manufacturers about the prequalification process and about dossier preparation and GMP compliance, in general

- Due to the lack of independent public standards for Levofloxacin and Prothionamide, USP DQI is working to develop monographs for these compounds

Conclusion and next steps

USP DQI will continue to partner with GDF to provide needed support to manufacturers of second-line anti-TB medicines in the areas of dossier preparation and GMP assessment of facilities. USP DQI desires to forge a more strategic partnership with the WHO prequalification program to facilitate the process and increase the pace of prequalification of second-line anti-TB products. In the short term, the following action items are being planned by USP DQI:

- Obtain from GDF an updated list of manufacturers that responded to the recent Expression of Interest and are approved to participate in GDF tenders. A condition for approval is that they participate in the prequalification process. USP DQI will be assigning resources to help these manufactures prepare for prequalification.
- Plan and meet with the WHO prequalification team in Geneva to map out a way forward in our relationship and to coordinate our respective activities. USAID assistance will be needed to facilitate this meeting.
- Organize a micro-planning workshop for Brazilian manufacturers of second-line anti-TB medicines and work with them to develop a plan for prequalification of their products. USP DQI and Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS) will work together on this venture. USP DQI plans to sponsor a member of the WHO prequalification program to attend the workshop.
- Follow up with manufacturer in Russia (SIA International) and provide initial guidance for prequalification of their second-line anti-TB medicines. A USP DQI staff member will visit the company in April 2009 to start initial discussions.



**A NEW
PERSPECTIVE
ON TB DRUG
PROCUREMENT.**

SUPPLY STAKEHOLDERS' MEETING FOR 2nd LINE ANTI-TB DRUGS (DRAFT)

RIO DE JANEIRO, MARCH 18 - 19, 2009

Day One: Wednesday, March 18, 2009

- 12:30 Joint Lunch (First and Second Line Drugs)
- 13:00 Perspectives and Opportunities of the Stop TB Partnership **Dr Marcos Espinal
Executive Secretary**
- 14:00 WELCOME ADDRESS AND INTRODUCTION OF PARTICIPANTS
WHAT'S COMING UP FOR SLD **Robert Matiru**
- China meeting
 - Diagnostic projects
 - World focus on MDR-TB
- 14:20 WHAT'S NEW IN THE GDF SUPPLY CHAIN CYCLE **Robert Matiru
Anahitta Shirzad
Thierry Cordier Lassalle
Robert Matiru
John Loeber**
- Growth of the GDF Team
 - UNITAID-funded Procurement
 - OMS/QM
 - Stockpile/Strategic Revolving fund - Challenges
 - Tendering
- 15:10 ACCELERATING ACCESS TO SECOND LINE DRUGS **Lorenzo Witherspoon**
- 15:45 **COFFEE BREAK**
- 16:00 USP DQI PRESENTATION **Patrick Lullaly**
- services available to suppliers
- 16:45 ADDRESSING PARTNERS CONCERNS **Robert Matiru
John Loeber
Thierry C- Lassalle**
- GDF address pre-submitted/selected concerns
 - Question and answer period
- 18:00 Closing Remarks **John Loeber**

Day two: Thursday March 19, 2009

- 9:00 Summary of the day before **John Loeber**
- 9:15 FORECAST **GLC/GDF rapporteuring**
- discuss forecasts previously sent to partners
 - outline future forecasting needs/plans
- 10:15 **COFFEE/TEA BREAK**
- 10:30 FORECASTING **John Loeber
Bruce McCreedy**
- Question and Answers re: Forecasting presentation
 - Round Table Discussion
- 11:15 WORKING GROUPS - SECOND LINE DRUGS
- separate into working groups to address ongoing issues with Second Line Drugs
 - Groups to be finalized during STM



**A NEW
PERSPECTIVE
ON TB DRUG
PROCUREMENT.**

12:30 - 13:45 LUNCH

13:45 WORKING GROUP PRESENTATIONS
- Working groups present their discussion and solution points

15:00 APPROACH TO TENDER **Mario Stassen**

15:45 COFFEE BREAK

16:00 SPEED MEETING
- 15 minute meetings on pre-submitted topics
- **Groups:**
- Quality Assurance/Quality Control
- Registration and Product Planning
- Tender
- Operational Issues

17:15 Wrap up and closing remarks **John Loeber**



**GLOBAL DRUG FACILITY
INFORMATION SESSION FOR POTENTIAL SUPPLIERS**

RIO DE JANEIRO, BRAZIL

Friday, March 20, 2009

**A NEW
PERSPECTIVE
ON TB DRUG
PROCUREMENT.**

9:00	WELCOME ADDRESS AND INTRODUCTION	Robert Matiru
9:10	PERSPECTIVES AND OPPORTUNITIES OF THE STOP TB PARTNERSHIP	Dr Marcos Espinal Executive Secretary
9:25	INTRODUCTION TO GLOBAL DRUG FACILITY MANDATE, PRODUCTS AND SERVICES, FINANCING	Robert Matiru
10:15	COFFEE/TEA BREAK	
10:30	OUTLINE OF GDF PROCUREMENT PROCESS	John Loeber
11:20	USP DQI SUPPORT PROGRAMME	Patrick Lukulay
11:40	PODIUM DISCUSSION ON STAKEHOLDER INVOLVEMENT	Facilitator: Lorenzo Witherspoon
12:30	LUNCH BREAK	
13:45	PRESENTATION OF GDF QUALITY REQUIREMENTS	Paloma Lerga
14:30	INTRODUCTION TO WHO PREQUALIFICATION PROGRAM	Janos Pogany
15:30	COFFEE/TEA BREAK	
15:45	WHO PREQUALIFICATION (CONTINUED)	
16:30	QUESTIONS & ANSWERS, FEEDBACK	Robert Matiru
17:30	CLOSE	Robert Matiru

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USP Drug Quality and Information Program

Global Drug Facility Super Team Meeting
Rio De Janeiro, Brazil ♦ March 17-19, 2009

**USP DQI Technical Assistance in GMP
for Second-line Anti-TB Medicines**

Patrick Lukulay, Ph.D.
Director, USP Drug Quality and Information Program




United States Pharmacopeia (USP)

USP Drug Quality and Information Program

- ♦ Founded in 1820, non-profit organization establishes officially recognized standards for medicines quality
- ♦ Only nongovernmental pharmacopeia in the world
- ♦ Over 500 staff and four laboratories in the U.S., India, China, and Brazil
- ♦ Over 600 volunteers on USP Expert Committees




USP Drug Quality and Information Program

USP Drug Quality and Information Program

- ♦ Cooperative agreement between USP and USAID
- ♦ October 2000–September 2010
- ♦ **Objectives:**
 - ▶ Develop or strengthen quality assurance and quality control systems in developing countries
 - ▶ Increase availability and use of unbiased drug information
 - www.uspdqi.org

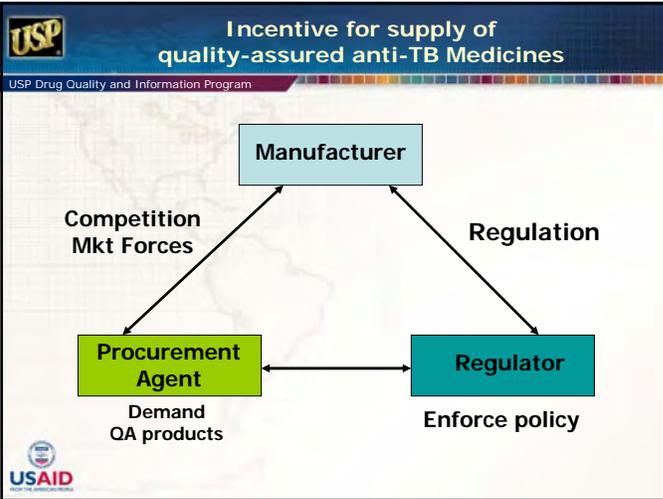



Where USP DQI Works

USP Drug Quality and Information Program

- ♦ **Africa**
 - ▶ Benin, Ethiopia, Ghana, Liberia, Madagascar, Mali, Senegal, and Uganda
- ♦ **Southeast Asia**
 - ▶ Cambodia, Laos, Philippines, Thailand, Vietnam, and Yunnan Province of China
- ♦ **Latin America**
 - ▶ Bolivia, Brazil, Colombia, Ecuador, Guyana, Paraguay, Peru, and Suriname
- ♦ **Europe/Eurasia**
 - ▶ Russia





- ### USP Focus on the Manufacturer
- USP Drug Quality and Information Program
- #### Barriers to large-scale effective treatment
- ◆ Limited number of pre-qualified second line anti-TB medicines
 - ▶ Poor quality dossiers submitted
 - ▶ Lack of GMP compliance
 - ▶ Poor understanding of the requirements for pre-qualification
- USAID

- ### USP Technical Assistance
- USP Drug Quality and Information Program
- ◆ **Focus on Manufacturer**
 - ▶ Provide technical assistance in GMP
 - Conduct on-site assessment of facilities
 - Review processes prior to pre-Q audits
 - ▶ Review and provide input to strengthen quality of submitted dossiers
 - ▶ Expedite WHO pre-Q process by increasing company readiness for inspection
 - ◆ **DQI as your Broker**

We do not approve your application but we facilitate the approval by WHO prequalification
- USAID

- ### USP How We Work
- USP Drug Quality and Information Program
- 
- ◆ Obtain list of priority second-line anti-TB meds from GDF and TB Drug Mgmt Sub-Working Group (SWG)
 - ◆ Identify and select potential manufacturers with GDF and SWG using pre-defined questionnaire
 - ◆ Provide technical assistance in GMP and dossier prep
 - ◆ Establish regular communication with those selected
 - ◆ Encourage manufacturer to submit documentation
- USAID

USP **Dossier Screening**

USP Drug Quality and Information Program



- ◆ Receive dossier from manufacturer prior to WHO pre-Q submission
- ◆ Screen dossier for completeness using checklist based on WHO pre-Q guidelines
- ◆ Review dossier for accuracy of info provided
- ◆ Identify deficiencies and omissions, provide appropriate recommendations
- ◆ Work with manufacturers to submit dossier to WHO pre-Q team
 - ▶ review findings of the WHO pre-Q team
 - ▶ assist manufacturers to address gaps

USAID

USP **GMP Inspection**

USP Drug Quality and Information Program




- ◆ Conduct on-site GMP inspection to prepare manufacturer for pre-Q audit
- ◆ Validate integrity of data submitted
- ◆ Collect samples
- ◆ Conduct full pharmacopeial monograph analysis and reporting

USAID

USP **Follow-up**

USP Drug Quality and Information Program




- ◆ Maintain up-to-date info on WHO requirements and deadlines
- ◆ Share info with manufacturers, dedicate DQI staff to respond
- ◆ Provide periodic updates to GDF regarding status of dossier preparation

USAID

USP **Examples of DQI Assistance**

USP Drug Quality and Information Program

- ◆ In collaboration with GDF, identified two manufacturers in India for technical assistance
 - ▶ Capreomycin injectable
 - ▶ Kanamycin
- ◆ Supported one manufacturer to submit dossier to WHO pre-Q team
 - ▶ Reviewed dossier prior to submission in Nov 2008
 - ▶ Dossier accepted for review in Dec 2008
 - ▶ Now reviewing WHO pre-Q comments on dossier with manufacturer
- ◆ Maintain Help Desk for follow-on questions from manufacturer

USAID

USP **Public Standards**

USP Drug Quality and Information Program

- ◆ Develop USP Pharmacopeial monographs in collaboration with manufacturers
 - ▶ Levofloxacin
 - ▶ Prothionamide



USP-NF

Monographs for Levofloxacin and Prothionamide Tablets will be added to *USP-NF*

USAID

USP **Zinc Sulfate Success Story**

USP Drug Quality and Information Program

- ◆ USP DQI provides TA to Rodael/Nutriset to produce zinc tablets of pharmacopeial and GMP standards
 - ▶ **Apr 2005:** UNICEF audits zinc tablet production; manufacturer does not meet WHO GMP
 - ▶ **Nov 2005:** USP DQI assesses, recommends changes, and provides TA on manufacturing, stability, and quality assurance issues
 - ▶ **Apr 2006:** USP DQI prepares Rodael for UNICEF audit
 - ▶ **May 2006:** Rodael passes UNICEF audit, named first qualified manufacturer of Zinc Sulfate for global supply

USAID

USP **Zinc Sulfate Success Story**

USP Drug Quality and Information Program

- ◆ **May 2006:** USP DQI works with Square Pharmaceuticals, Bangladesh manufacturer of Zinc Sulfate
- ◆ **May 2008:** Square becomes second UNICEF qualified manufacturer for Zinc Sulfate

USAID

USP **Conclusions**

USP Drug Quality and Information Program

- ◆ One barrier to large-scale treatment of MDR-TB — address by increasing number of quality-assured second-line anti-TB medicines
- ◆ Effective TA to manufacturers — local and multinational — is greatly needed
- ◆ DQI positioned to assist manufacturers to obtain WHO prequalification
 - ▶ Dossier preparation and guidance toward prequalification
 - ▶ GMP assessment to prepare manufacturers for audit inspection

USAID

Questions?



Thank You

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<http://www.usp.org/worldwide/dqi/WHOQualificationRequest.html>

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Adtl Info: How to make GMP Affordable

USP Drug Quality and Information Program

- ◆ Risk Based Audit
 - ▶ What really matters/Nice to have
 - ▶ Remediate gaps to keep supplies coming
- ◆ Make Products cost effective
 - ▶ Reduce input cost- Improve chemistries
 - ▶ Reduce risks- better forecasting
 - ▶ Pooled procurement- increase volume
- ◆ Technical Assistance at no cost to manufacture
 - ▶ Evaluate Processes and procedures
 - ▶ Facilities audits
 - ▶ Third Party testing of products

