

**Promoting the Quality of Medicines (PQM) Program
Quarterly Reports: FY14 Activities (October 1, 2013–September 30, 2014)**

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Cross Bureau K. Chibwe					
Increase awareness about the importance of medicines quality					
Attend/present at national, regional, and int'l conferences		<p>Dr. Hajjou presented at the SciX 2013 Conference in October in Milwaukee, WI.</p> <p>Dr. Chibwe presented at the ASTMH Global Health Conference in November in Washington, D.C.</p>	<p>Dr. Chibwe presented “Science Diplomacy and Global Health” at Georgetown University’s Medical School in February.</p> <p>Dr. El Hadri and Dr. Hajjou gave four presentations at the Global Health Mini-University at George Washington University in March.</p>	<p>Dr. Lukulay presented on securing the supply of quality-assured medicines in developing countries at Johns Hopkins University in April.</p> <p>Ms. Krech presented on the Medicines Quality Database at the Unite for Sight 11th Annual Global Health and Innovation Conference at Yale University in April.</p> <p>Dr. Lukulay presented at the “Novartis Malaria Initiative: Best Practices Workshop” in Dar es Salaam, Tanzania in June.</p>	No presentations given
Use available media outlets to advocate need for medicines QA		<p>USP issued three press releases related to PQM. These promoted PharmaCheck, the PQM program extension, and USP’s membership in the “Fight the Fakes” campaign.</p>	<p>An editorial on the Medicines Quality Database (MQDB) was published in the Jan 2014 issue of the Bulletin of the World Health Organization.</p>	<p>USP issued two press releases promoting PQM activities related to improving access to TB medicines and the field testing of FDA’s CD-3 device at CePAT in Ghana.</p> <p>PQM contributed to a USP blog post on medicines quality in the supply chain.</p>	<p>PQM submitted three case studies—on successful activities in Liberia, Ghana, and Cambodia--for the HSS Global Call for USAID flagship projects.</p> <p>USP issued two press releases promoting PQM activities, one on the CePAT lab becoming ISO 17025 accredited and one on the PharmaChk device receiving a transition-to-</p>

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					scale grant from Saving Lives at Birth.
Produce up-to-date information about current issues in medicines quality					
Collect and publish reports of incidents of poor-quality medicine use	M McGinnis	38 reports were added to the <i>Media Reports on Medicine Quality</i>	34 reports were added to the <i>Media Reports</i>	10 reports were added to the <i>Media Reports</i>	25 reports were added to the <i>Media Reports</i>
Maintain and update PQM website	M Foster	4 new stories, 5 photos, 2 videos, and 3 new or updated resources were added	Added 7 articles and 8 photos; updated 2 webpages; added 12 new resources and updated 3	Added 8 articles and 7 photos; updated 2 webpages; added 3 new resources	Added 7 articles and 8 photos; updated 3 webpages; added 7 new resources
Support regional approaches and networks					
Participate in NEPAD's Technical Working Groups (TWG)		Dr. Smine participated in a meeting of the African Medicines Regulatory Harmonization TWG, held in November in South Africa.	Mr. Boateng participated in TWG meetings held in South Africa in March.	NEPAD designated 10 institutions as Regional Centers of Regulatory Excellence (RCOREs) in May and has prepared a draft RCOREs Guide; the RCOREs have submitted their curricula to NEPAD.	A NEPAD meeting was held in Aug in South Africa; the group prepared two guides (for the Africa Medicines Fellowship Programme and for RCOREs), a TOR for the RCOREs Governing Board, and a plan of action for NEPAD-USP CePAT
Explore improved tools to ensure quality control or to increase the knowledge base about quality assurance					
Develop a field-based QC tool with increased accuracy, sensitivity, and reliability: <ul style="list-style-type: none"> – Develop prototype – Field test & pilot – Develop platform for broad class of meds/ monographs 	K Chibwe	Boston University (BU) is working with the design firm, Fikst, to develop an Alpha-prototype (field-ready), expected by Jan 2014. Artesunate and tetracycline will be used for the initial field tests in Ghana. BU is working with PQM to finalize the	Dr. Chibwe and representatives from BU and the Center for Integration of Medicine and Innovative Technology conducted field studies at USP's CePAT facility in March. Results of the studies will be available in Q3.	Dr. Chibwe and Mr. Roth visited BU to carry out further post-field testing at the University. Results from the BU trip and the Ghana field studies were reported in two trip reports. While the artesunate injectables matched the HPLC data well, further refinement	PharmaChk device received a \$2 million transition-to-scale grant from Saving Lives at Birth: A Grand Challenge for Development. This funding will help further the development of PharmaChk. Optamer development is

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		protocol for the field studies and carrying out validation work as well.		work will be needed for tablets testing optimization.	ongoing for oxytocin and cotrimoxazole.
Core Tuberculosis		A. Hong			
Increase the supply of quality-assured second-line TB medicines					
Continue to provide TA to identified API & FPP mfrs of SL-ATBs seeking WHO PQ		<p>Shalina: dossier submitted to WHO; accepted and inspection scheduled for Q2</p> <p>Varichem: dossier submitted to WHO but not accepted; will complete per WHO's request and resubmit</p> <p>Steril-Gene: dossier received for review but not in CTD format; committed to revising into new format</p> <p>Peili: IVD study protocol reviewed and provided comments</p>	<p>China: Qilu: dossier received for review; comments provided to company for incorporation Fuzhou: WHO inspection in February Xinhua: process validation to be repeated per WHO</p> <p>India: Concept: reformulated FPP and in process of technology transfer Shalina: currently dossier on hold for review due to API site refusal of inspection by WHO Steril-Gene: updated dossier received for review</p> <p>Indonesia: Zenith: implementing CAPA; plans to conduct IVD study</p> <p>Korea: Dong-A: cycloserine API PQ submission</p>	<p>China: Hisun Pharma: received WHO PQ for Capreomycin API in May 2014; FPP listing expected in July/Aug 2014 Zhejiang Langhua: received WHO PQ inspection closing letter in June 2014; APIMF closing letter issued Fuzhou: working on implementing CAPA from WHO inspection; also submitted second APIMF for non-sterile kanamycin API Allsino Chemical Co.: product development completed NCPC Formulation Co: dossier compilation in progress – scheduled to submit in Q4</p> <p>Georgia: GM Pharma: new project – potential visit Q4</p> <p>India: Concept: working on</p>	<p>China: Hisun Pharma: received WHO PQ for Capreomycin FPP in Sep Fuzhou: visited in Sep to follow up with CAPA from WHO inspection Silver Eagle: will revise PV protocols to implement PQM comments Hebei Shengxue Dacheng: will follow up with potential assessment in FY15 Q1 Hebei Xingang: provided assistance in new plant and process design NCPC Group Corp: expected to submit dossier in FY15 Q1 Pen Tsao: potential OEM partner for Clofazimine API Neo-Dankong: working on dossier for submission</p> <p>Georgia: GM Pharma: new project – potential visit FY15 Q1</p> <p>Ghana: Entrance Industries:</p>

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			<p>tentatively scheduled for Sep 2014; Terizidone FPP BE study protocol final and contract is in process Yuyu Pharm: GMP assessment conducted Enzychem: reviewed APIMF and provided comments for incorporation BCWP: visited existing facility – reviewed cleaning validation, some quality SOPs, process validation protocol CKD: GMP assessment conducted KUP: met to discuss timeline and potential GMP assessment in June 2014 Hankook/Korus Pharm: new project – general discussion on potential path toward WHO PQ Ildong; new project – general discussion on potential path toward WHO PQ Theragenetex: general meeting to discuss timeline for formulation development and facility construction</p> <p>Nepal:</p>	<p>compiling dossier Shalina: reformulating with new API source Steril-Gene: working on compiling dossier for PQM review</p> <p>Indonesia: Zenith: implementing CAPA; plans to conduct IVD study Sanbe: implementing CAPA Kalbe: new project – potential assessment in Q4</p> <p>Korea: Dong-A: cycloserine API PQ submission tentatively scheduled for Sep 2014; Terizidone FPP BE study protocol final and contract is in process Enzychem: submitted to WHO for API PQ BCWP: visited site to follow up on construction and provide input on HVAC, Water plans CKD: conducted site visit to discuss proposal for HEPA installation construction CKD Bio: new project – potential site visit in Q4 KUP: received qualification documents</p>	<p>review and comment on SMF</p> <p>India: Shalina: dossier is complete but facility preparation may take 8-12 months Steril-Gene: Dossier had to be reformatted</p> <p>Indonesia: Zenith: implementing CAPA; site visit scheduled for Nov 2014 Sanbe: implementing CAPA; site visit scheduled for Nov 2014 Kalbe: site assessment scheduled for Nov 2014</p> <p>Korea: Dong-A: Terizidone FPP BE study initiated and contract complete; review and comment on proposed analytical methods Enzychem: submitted APIMF in Jun 2014; working on response to WHO query (not yet accepted) BCWP: construction still in progress; local GMP certification scheduled for Aug 2015 CKD: construction</p>

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			<p>DJPL: draft dossier reviewed but incomplete; committed to manufacturing pilot scale in late February</p> <p>Philippines: Hizon: dossier received for review Lloyd's: currently in FPP formulation development Unilab: dossier received for review</p> <p>Taiwan: Peili: IVD completed; dossier compilation in progress</p> <p>Zimbabwe: Varichem: API manufacturer committed to submitting APIMF in spring</p>	<p>for review Ildong; new project – potential site visit in Q4 Hanmi Fine Chemicals: new project – potential site assessment in Q4</p> <p>Morocco: Pharmis: new project – potential visit in Q4 Pharma 5: new project – potential visit in Q4 Galenica: new project – potential visit in Q4</p> <p>Nepal: DJPL: completed pilot scale batches; conducted IVD study; 3-mo stability data received for review</p> <p>Philippines: Hizon: site assessment conducted in April Lloyd's: IVD study in progress Unilab: site assessment conducted in April</p> <p>Taiwan: Peili: IVD completed; dossier compilation in progress</p> <p>Vietnam: Imexpharm: site assessment conducted in May</p>	<p>scheduled for Aug 2015 CKD Bio: in support of Indonesian companies KUP: review of SMF and provide comments for revision Ildong; new project – potential site visit in FY15 Q1 Hanmi Fine Chemicals: conducted site assessment in Aug 2014; API DMF ready for submission but will need to update zone 4b stability data (to start in Oct 2014) Seoul Pharma: New project initiated Aug 2014 Hankook Korus Pharma: new project re-initiated in Aug 2014 HUONS: new project initiated in Aug 2014</p> <p>Mexico: Interquim: new project; potential visit Oct 2014</p> <p>Philippines: Hizon: dossier submission scheduled for FY15 Q1 Lloyd's: will be building a new facility Unilab: dossier submission scheduled for FY15 Q1</p> <p>Taiwan:</p>

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				<p>Zimbabwe: Varichem: API manufacturer committed to submitting APIMF in spring</p>	<p>Peili: dossier received for review – needs to be re-organized and two doses separated; tentative site assessment scheduled for Dec 2014</p> <p>Vietnam: Imexpharm: currently working on CAPA</p> <p>Zimbabwe: Varichem: dossier submitted and accepted for review by WHO; awaiting inspection date for PQM mock audit scheduling</p>
<p>With GDF/WHO, conduct workshops in high burden countries; identify add'l mfrs not yet in PQM pipeline</p>			<p>Manila, Philippines: 10 manufacturers from Thailand, Vietnam, Cambodia, and Philippines attended; 2 manufacturers from Vietnam and 1 manufacturer from Cambodia expressed interest; 3 from Philippines and 1 from Thailand have already initiated work with PQM</p> <p>Casablanca, Morocco: 20+ manufacturers attended from Morocco – 3 were visited by PQM staff during the trip; 3 more manufacturers</p>	<p>Jakarta, Indonesia: 21 attendees from Indonesian manufacturers attended the information session at CPhI Jakarta. After the information session, one-on-one meetings with manufacturers were held</p>	

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			have expressed interest		
Participate in GDF and WHO meetings with mfrs to discuss PQ					
Conduct operational research to identify substandard/counterfeit second-line medicines on the market					
Carry out PMS (if issues arise) of quality of second-line medicines in the country markets				No issues have been brought to PQM's attention	
Develop OEM for at least two critical second-line anti-TB medicines					
Identify additional suppliers to implement the OEM model for select second- and third-line ATB medicines		Work with Baush Pharm and Interpharma Access in progress	Interpharma completed product development on Kanamycin; Baush Pharma completed product development on Capreomycin	Interpharma and Baush Pharma have both completed the registration batches and are working on compiling the dossiers for submission in Q4	PQM site assessments conducted in Aug 2014 for both Interpharma and Baush Pharma
Support research to improve quality and yield of Kanamycin through genetic engineering					
Identify research group with expertise in fermentation to carry out proof-of-concept for higher quality/yield				RFA is in final stages of review before being advertised.	RFA published
Support scale-up of technology to API manufacturer					
Provide support through capital investment to promising companies to obtain WHO PQ					
Obtain comparator products and assist select mfrs with funding for BE studies			CKD: Zyvox sent for formulation development Zenith: Levaquin sent for IVD DJPL: Levaquin sent for IVD Sanbe: Tavanic	Zenith: Levaquin sent for IVD (2 bottles resent due to short expiration date) Phapros: Levofloxacin comparator products Varichem: Levofloxacin comparator products Imexpharm: Levofloxacin RS and comparator products	Pharmis: Avelox and RS Entrance Industries: Levaquin and RS Hizon, Kalbe, Shalina, Varichem: Levaquin BE subsidy contract for Dong-A complete and ready for payment upon completion of BE study

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				Contract is being drafted to provide financial assistance for Dong-A to conduct a BE study on their second product	
Support calibration and validation of mfg and analytical equipment					
Provide assistance for other capital costs, as necessary					
Develop public standards (pharmacopeial and Minilab[®] methods) for screening quality of second-line anti-TB medicines					
Develop Minilab [®] test methods for SL-ATBs or third-line ATBs					
Develop USP monographs for prothionamide, terizidone					
Core Malaria	L Evans				
Conduct studies to monitor antimalarial medicines quality and the extent of diversion from the public to private sector					
Adapt study protocols for AM MQM study in new countries		Adaption of study protocols completed	Study completed in Ghana		
Conduct four new studies				Studies delayed in several countries due to Ebola outbreaks	Studies continue to be delayed in several countries due to Ebola outbreaks
Develop reports and disseminate results					
Conduct follow-on studies				Study completed in Nigeria	
Improve knowledge about the quality of antimalarials in PMI countries					
Obtain samples of meds requested by PMI				In progress	

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		Q1	Q2	Q3	Q4
team and test					
Increase the availability of standards and testing methods for selected antimalarials					
Develop monographs for pyronaridine API and pyronaridine-artesunate FDC				In progress	
Develop monographs for pediatric formulations of DHA-PIP FDC and/or pyronaridine-artesunate				In progress	DHA-PIP FDC medicines monograph developed.
Core Maternal Health and Child Survival		L. Evans			
Increase the supply of quality assured maternal, newborn and child health medicines					
Provide support to Chi Pharmaceutical for WHO PQ of zinc sulfate			Developed responses to WHO dossier queries related to excipients in terms of choice and compatibility. A PQ audit is tentatively scheduled for May 2014.		
Monitor maternal, newborn, and child health medicines quality					
Conduct medicines quality testing of maternal health commodities (in FY13 workplan; work being completed with carryover funds)		Performed assay analysis on 8 batches of vitamin A capsules from the Sudan for UNICEF. Full compendial analysis was performed on 4 batches of vitamin A capsules from 3 different manufacturers.		Completed QC analysis on one batch of Chlorhexidine gel samples.	
Develop CHX gel monograph for USP MC (in FY13 workplan; work being completed with carryover funds)			Monograph development began with sourcing of all potential impurities as identified in the USP, BP and EP	Monograph development continued with the start of method validation.	Validation of all monograph procedures was completed; the final report is being prepared for submission to the USP

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		Q1	Q2	Q3	Q4
			monographs for the API.		expert panel.
Support USAID medicines quality initiatives related to UN Commission Activities					
Participate in UN Commission activities/meetings		Led medicine quality and manufacturer GMP discussions and participated in bi-weekly teleconferences and the quarterly face-to-face meetings: Diarrhea and Pneumonia Working Group, Chlorhexidine Working Group, Maternal Health TRT, and the Injectable Antibiotics TRT	Provided input into the work plans, led medicine quality and manufacturer GMP discussions, and participated in bi-weekly teleconferences and quarterly face-to-face meetings: Diarrhea and Pneumonia Working Group, Chlorhexidine Working Group, Maternal Health TRT, and the Injectable Antibiotics TRT	PQM provided input into the development of the UN Commission workplans. PQM participated in the Pneumonia and Diarrhea Meeting and the Chlorhexidine working group quarterly face-to-face-meetings. PQM continued to participate in bi-weekly teleconferences with the Diarrhea and Pneumonia Working Group, Chlorhexidine Working Group, Maternal Health TRT, and the Injectable Antibiotics TRT	Continued to provide support to the Diarrhea and Pneumonia Working Group, Chlorhexidine Working Group, and other technical reference teams. PQM participated in the WHO and UNICEF manufacturers meeting and met with regulatory authorities and manufacturers to plan next technical visits and to provide technical assistance.
Conduct quality testing of zinc medicines sent by UNICEF, USAID, and other partners (in FY13 workplan; work being completed with carryover funds)		Conducted full compendial analysis for UNICEF of zinc sulfate tablet batches from 4 manufacturers to be used in the global zinc roll out.		Full compendial analysis was performed on several batches of zinc sulfate tablets from different manufacturers.	Completed QC analysis of zinc tablets submitted by partner. Full compendial testing was performed.
SUB-SAHARAN AFRICA					
Angola	R Okafor				
			Conducted the initial assessment of QA/QC capacities of Angola in collaboration with USAID (Maria Miralles)	Still awaiting Mission approval	At this point, PQM is not able to conduct any activities; we are waiting to re-initiate contact with new USAID in-country staff. After the Q2 assessment

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			<p>Drafted a study protocol and proposed an approach to establish a baseline of the quality of antimalarials in four regions and submitted it to the Mission for validation by the local partners. There is no functional medicines authority and no national QC lab in Angola.</p> <p>Awaiting mission approval to finalize the work plan, timeline, and budget</p>		<p>visit, there were activities pending for USAID/Angola to approve. However, as there are new Mission staff, USAID staff in D.C. will have to re-initiate contact to determine the next steps.</p>
Burundi	M Hajjou				
Strengthen the capacity of the INSP QC laboratory					
Establish a three-year implementation plan to strengthen lab capacity		Burundi activities will begin in Q3		USAID-PEPFAR contacts are reviewing the PQM workplan; activities will begin following approval	Work plan was approved
Equip the QC lab and train staff according to the first phase of the implementation plan					<p>One HPLC system and lab supplies were procured. The lab also received USP reference standards as part of the USP Technical Assistance Program.</p> <p>Two lab staff will receive training on QC testing at CePAT in Nov 2014</p> <p>PQM will train lab staff in HPLC in Dec 2014</p>

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		Q1	Q2	Q3	Q4
Support the improved governance of the national medicines regulatory authority (DPML)					
Assist the DPML to build its medicines regulatory capacity					PQM will acquire computer-based drug registration tool and facilitate training on its use in Dec 2014
– Establish the law and medicines regulation					
– Strengthen medicines registration system					
– Assist DPML to strengthen capacity for inspections					
Establish a national medicines quality monitoring system					
Implement use of basic tests as first step of QC for antimalarials – Procure Minilabs – Train analysts – Confirmatory testing – One round of MQM – Promote enforcement					On Minilab was procured. Discussions were held on the roles of each stakeholder in the planning and implementation of MQM activities. PQM will provide training in sampling and testing in Dec 2014
Ethiopia	Eshetu W.				
Strengthen marketing authorization (MA) of medicines and local medicine manufacturers					
Strengthen FMHACA Product Registration & Licensing Directorate					
Build capacity in dossier assessment, GMP/GCP inspections			Training on dossier evaluation was conducted Developed training materials on basic GMP and conducted training	Assisted in the assessment of 391 dossiers which have been in backlog for two years	Provided a 10-day advanced GMP training to 12 pharmacists from FMHACA and FBPI in Addis Ababa

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			in March for 31 staff from FMHACA, Veterinary Drugs and Feed Control and Administration and Authority, and the Food, Beverage and Pharmaceutical Development Institute		
Provide TA to develop tools, SOPs, etc., to operate MA		<p>Guidance provided on Training and Qualification Requirements for GMP Inspectors; Inspection of Foreign Pharmaceutical Manufacturers; Foreign Manufacturers Inspection Application Form; and GMP Inspection Report Writing.</p> <p>Strategy paper for the assessment of dossiers in backlog drafted and submitted to FMHACA</p>	<p>Reviewed and submitted the Medicine Manufacturing Establishment directive to FMHACA. The Directive is now under discussion</p> <p>Good Manufacturing Guidelines for Pharmaceutical Products-Basic Principles: was reviewed, edited, and submitted for printing</p> <p>USP/PQM staff supervised and guided the assessment of over 300 dossiers in backlog.</p> <p>Initiated review of the medicine registration guidelines, Common Technical Documents (CTD) which conform with ICH countries guidelines</p>	<p>Finalized and published Good Manufacturing Practices Guidelines for Pharmaceutical Products</p> <p>Finalized the Guidance on Training and Qualification Requirement of GMP Inspectors and submitted it to FMHACA</p> <p>Finalized Foreign GMP Inspection Application Form and reviewed it with FMHACA</p> <p>Finalized Guidance on Writing GMP Inspection Reports and submitted it to FMHACA</p> <p>Draft Medicine Manufacturing Establishment Directive reviewed and submitted to FMHACA</p> <p>Finalized Directive for foreign medicine</p>	<p>Drafted:</p> <ul style="list-style-type: none"> • GMP inspection manual • Biological manufacturers GMP inspection checklist • Guideline for variation application • Guidance for Biowaver of medicines • Long term strategic document for conducting dossier assessment and GMP inspection • Terms of reference for external experts • Declaration of Interest for external experts • GMP and GCP fee structure <p>Technical assistance provided to the newly established medicine inspection directorate</p>

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			<p>Initiated review of the medical devices registration guidelines</p> <p>One staff from USP/PQM participated in a workshop on the development of traditional medicines guidelines organized by FMHACA at Bishoftu in February</p> <p>Meetings conducted with School of Pharmacy, Addis Ababa University; Ethiopian Veterinary Drug and Feed Administration and Control Authority; Beverage, Food, and Pharmaceutical Development Institute to discuss future collaborative work</p> <p>Technical assistance provided to Cadela Pharmaceutical regarding bioequivalence study waiver and comparator products selection</p>	<p>manufacturers GMP inspection</p> <p>Guidelines for registration of medicines common technical document (CTD) reviewed and posted on FMHACA's website</p> <p>Guidelines for registration of medical devices drafted</p> <p>Developed draft Guidelines for Submission of Medicine Variations Application</p> <p>Guidance for biowaiver draft prepared and is being reviewed</p> <p>Inventory of tools essential for effective regulatory management was developed and submitted to FMHACA to be used for self-assessment</p> <p>Preparatory work in progress to send five regional medicine inspectors for training on inspection principles and techniques at CePAT, Ghana</p> <p>Preparations in progress</p>	<p>Updated seven different medicines registration checklists as per the new guideline for registration of medicines</p> <p>Guideline for Registration of Medicines and Guideline for Registration of Medical Devices approved by FMHACA and in the printing process</p>

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				for a ten-day training on advanced GMP to be held in Addis Ababa	
Support to develop or adopt data and info management system			Two USP/PQM staff participated in an IT meeting organized by USAID/Ethiopia in Feb		
Train staff to operate and manage system					
Strengthen FMHACA's quality control laboratories to become compliant with cGMP, ISO 17025 accredited, and WHO Prequalified					
Strengthen FMHACA Product Quality Assessment Directorate (PQAD)					
Maintain 7 ISO accredited methods		PQAD lab was re-assessed and found to be compliant with ISO requirements for the seven test methods; accreditation was extended for two years		<p>Training on analytical method validation given to 18 FMHACA staff in Apr</p> <p>Report on qualification of VALENDOR branded instruments prepared by VALENDOR and submitted to USP</p> <p>A two-week hands-on training was provided for 4 branch FMHACA staff on basic analytical techniques and quality management systems in Jun-Jul at FMHACA'S Product Quality Assessment Directorate Laboratory</p>	Agreement signed between USP and PQAD to provide USP reference standards and USP publications to PQAD
Obtain WHO PQ for same 7 methods		Preparations for WHO PQ were initiated and the laboratory information file (LIF) and expression of interest were submitted to WHO	Proficiency testing results for six physicochemical test methods were obtained from RTC PT provider; results were found to be	A three-day visit by the WHO assessor was carried out; the assessor's report identified the gaps observed and expected	

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			acceptable	corrective actions	
Move condom lab to new site; get ISO accredited					
Move microbiologic lab to new site, calibrate/qualify equipment					
ISO accredit additional test methods					
Have labs participate in QMS, proficiency tests		The lab participated in PT organized by RTC-sigma-Aldrich Corporation for six physico-chemical test methods	The lab participated in PT organized by RTC-sigma-Aldrich Corporation for six physico-chemical test methods		The condom lab participated in PT organized by FHI-360 and Enersol
Support FMHACA to maintain, calibrate, and qualify lab equipment			Paperwork was finalized to get waiver for maintenance of condom machines	Maintenance and qualification of VALENDOR condom testing machine carried out in May; the machine is operational	Supported maintenance and qualification of Enersol condom QC instruments and training for 4 FMHACA staff on condom testing machine maintenance Supported calibration of 61 PQAD instruments by CCG of Egypt Supported maintenance of 2 HPLCs, 1 AAS, and 1 FTIR for PQAD
Train staff in test methods and QMS					
Train staff in condom QMS (ISO 4074)					Supported training of 4 PQAD staff on female condom QC methods and ISO 4074 at Valender lab

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					in Mauritius
Train staff in microbiological test methods					
Strengthen post-marketing surveillance of AM, ARV, and OI medicines circulating in Ethiopia					
Train participating staff in sampling & testing			Training was organized for PMS sample collectors; a report was submitted to USAID		
Develop generic guideline and protocols for PMS of AM, ARV, OIs meds		Generic PMS guidelines were developed The PMS protocol was prepared for conducting PMS of ARV and OI medicines	Protocol was prepared for conducting PMS of ARV and OI medicines		
Support & coordinate sampling of AM, ARV, OI meds per protocols		USP reference standards for testing ARV and OI medicines were procured and supplied to FMHACA	Sample collection of selected ARV and OI medicines was carried out at four sites: Borena, Jijiga, Metema, and Addis Ababa	Collection of samples of antimalarial, ARV, and OI medicines completed from all eight sites	
Support testing of AM meds per protocol				Necessary input supplied to the laboratory; testing of the collected samples has begun	Sub-award signed between USP and FMHACA to pay per-diem for PMS testing activities
Support testing of ARV & OI meds per protocol			Lab supplies for PMS of selected ARV and OI medicines were procured and supplied to FMHACA Reference standards for testing ARV and OI medicines were purchased and provided	Necessary input supplied to the laboratory; testing of the collected samples has begun	Testing of PMS samples finalized

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			to the lab		
Support FMHACA in fight against illegal trade of medicines through workshops & seminars; encourage regulatory actions		A proposal to establish a national taskforce to combat the illegal trade of food and medicines was prepared and submitted to FMHACA, USAID/Ethiopia, and USP/PQM		In May and June, three workshops (in Amhara and Tigray regions) were organized to promote public awareness of the illegal food and medicines trade	
Assist local medicines manufacturers toward GMP compliance and WHO Prequalification					
Improve knowledge and skills of local med manufacturers in GMP					
Get local OI mfrs to get products QA'ed					
Support local mfrs in implementation of GMP Roadmap					Provided advanced GMP training to 11 staff from local manufacturers
Strengthen FMHACA's branch quality control laboratories to become capable of monitoring the quality of medicines					
Conduct needs assessments of branch laboratories		Tool for rapid assessment of FMHACA branch labs was developed	Assessments of four FMHACA branch laboratories were conducted Workplan to develop the branch labs was drafted and is being discussed with FMHACA		
Support branch labs based on needs assessment				Lab instruments were installed at the FMHACA Southern Branch lab and training was provided to the staff on how to use the instruments	
Strengthen FMHACA's branch quality control laboratories to become capable of monitoring the quality of medicines					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct needs assessments of branch laboratories		Tool for rapid assessment of FMHACA branch labs was developed	Assessments of four FMHACA branch laboratories were conducted Workplan to develop the branch labs was drafted and is being discussed with FMHACA		
Support branch labs based on needs assessment					
Strengthen regional/city administration medicine food and healthcare control and administration bodies					
Development of assessment tool		Tool developed for rapid assessment of regional/city administration medicine, food, and healthcare regulatory bureaus. Preliminary discussions with Addis Ababa City Administration and Oromia Regional Bureau carried out			
Assessment of five regional/city administration agencies			Assessments of Amhara and Tigray Regional Food, Medicine and Healthcare regulatory core processes were undertaken in Jan and Feb and reports submitted to HQ to be reviewed and edited	Assessment of the Oromia Regional Food, Medicine and Healthcare Regulatory Core Processes shared with USP/HQ and Oromia region Assessments of Southern Nations Nationalities and Peoples Regional Health and Health-related Services and Products	Training on regulatory inspection and health system supervision was provided to staff from 5 regional/city administration regulatory agencies

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Quality Control Authority conducted and report shared with the region	
Assist Pharmaceutical Funds and Supply Agency (PFSA) in establishing internal quality control laboratory					
Develop assessment tool		Tool developed			
Conduct assessment		Assessment of the QC needs of PFSA was completed	Workplan prepared based on the assessment results		
Ghana	R. Okafor				
Support post-marketing surveillance of antimalarial medicines at seven sentinel sites					
Conduct two rounds of MQM at selected sites for testing			To be completed in Q3; MQM contractual delay	Funds were transferred to the FDA Ghana account in April, after months of contract delays, to complete FY13 activities and initiate FY14 sampling and collection	MQM for MCH and antimalarials is ongoing; PQM sent 5 vials of Ergometrine and Oxytocin RS for the testing
– Conduct confirmatory testing of R1 at FDA lab		Round 1 confirmatory testing completed for FY13	To be completed in Q3; MQM contractual delay	FDA Ghana completed confirmatory testing and sent a report to PQM	FDA Ghana is working on testing the MQM samples; confirmatory testing will occur in Oct
– Conduct confirmatory testing of R2 at CePAT			To be completed in Q3	Funds for the FY14 first milestone were sent to FDA Ghana in June; sampling has begun for both PMI and MCH projects	Testing is ongoing
Conduct onsite evaluations of selected sites (PQM-FDA team)			To be completed in Q3; MQM contractual delay	Training planned at FDA site by select FDA team and PQM consultant	Training was completed; sampling and testing are ongoing
Promote enforcement actions based on data			To be completed in Q3; MQM contractual delay	In progress, based on finalized results	As there are no confirmed results yet, no enforcement actions have been taken; only Minilab

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					preliminary results are available
Strengthen the capacity of the national Food and Drugs Authority QC laboratory and assist toward ISO 17025 accreditation					
Assess FDA lab QMS, equipment qualification/calibration		Provided key consumables needed for accreditation: HPLC columns, parts for dissolution, thermohygrometer, digital thermometer, stop watches, safety consumables	Facilitated with in-country representatives to service key equipment for ISO 17025 accreditation	Procured key supplies and consumables necessary for accreditation; assisted the lab to revise key documents and submitted them to the accreditation body	FDA Ghana lab received official accreditation in Jul 2014; PQM worked with the lab to correct the findings from the accreditation body
Train staff as needed based on assessment		Installed key equipment for the scope of accreditation; offered training in GDP, Safety in the Lab, Karl Fischer, FTIR, and ISO 17025	Trained staff on Karl Fischer, root cause analysis, loss on drying, effectively reading and understanding the pharmacopeia, and uniformity of dosage unit	Conducted several technical and ISO/QMS trainings to prepare staff for the audit; conducted a mock audit session to prepare staff	All trainings for the accreditation were completed prior to Q4 to prepare the lab for accreditation. Follow-up activities will ensue to ensure maintenance of accreditation status
Provide QMS training to FDA QA team		Trained QA staff on how to conduct good corrective and preventive actions; reviewed CAPAs with QA team; facilitated proper arrangement of sample receipt room under QA	Internal auditing training provided to key QA personnel and lab appointed auditors	FDA QA team was trained on how to answer audit questions; final documents were reviewed with the QA team before submission	All trainings for the accreditation were completed prior to Q4 to prepare the lab for accreditation. Follow-up activities will ensue to ensure maintenance of accreditation status
Facilitate pre-accreditation audit		Selected key staff to perform demonstration of test during audit	Pre-audit was conducted by PQM; official audit is scheduled for Apr 2014	PQM provided the technical assistance necessary for the pre-audit	
Provide TA post-audit with CAPAs		Trained QA staff on how to conduct good corrective and preventive actions; reviewed CAPAs with	Assisted and reviewed corrective actions with QA and provided feedback for corrections	Assisted the FDA to resolve all corrective actions in the system and from previous PQM audits	All corrective actions were completed and forwarded to the accreditation body; official accreditation was granted

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		QA team; facilitated proper arrangement of sample receipt room under QA			in Jul 2014
Facilitate ISO 17025 accreditation pre-audit and ACLASS audit		Reviewed key SOPs and quality manuals and offered recommendations and corrections	Submitted all documents to ACLASS and scheduled accreditation assessment for Apr 2014	ACLASS audit took place in April. PQM assisted with solving all CAPAs and submitting them to ACLASS. FDA became officially accredited in Jun 2014	PQM is now preparing the lab for the surveillance audit, when ACLASS will visit the lab to ensure it is still in compliance. PQM has discussed with the lab director adding additional tests to the accreditation
Provide training for FDA GMP Inspections staff in risk-based compliance module; strengthen capacity of GMP Inspectorate Quality System					
Provide FDA Inspectors with GMP assessment training			Planned for Q3-Q4	GMP training for inspectors has been planned for July. A meeting with key FDA participants was conducted in June outlining what is expected for this training	GMP training took place at FDA Ghana with key inspectorate in Sep 2014
Improve internal system of GMP Inspectorate			Planned for Q3-Q4	Planned for Q4 – in progress	Training took place at FDA with necessary tools for internal FDA inspectors
Support inclusion of FDA data in the PQM MQDB					
Support data entry and develop statistics using MQM data			Data available from MQM first round provided for MQDB	MQM data from round 1 was provided to PQM consultant for MQDB and for journal paper and analysis	FDA completed, and available data was provided to PQM. Once second round of data is completed, it will be included in the database
Collaborate with the Maternal Health Channel of Creative Storm Network to develop advocacy and public sensitization programs					
Produce short documentary on PMS process			Planned for Q3-Q4	Based on meeting and discussion with USAID, PQM emphasis is to	Since emphasis is to remain on MQM, PQM provided all necessary

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				remain on MQM testing and provision of results	tools, consumables, and standards for MCH testing
Facilitate public policy dialogue through radio and TV discussions			Planned for Q3-Q4	Based on meeting and discussion with USAID, PQM emphasis is to remain on MQM testing and provision of results	Since emphasis is to remain on MQM, PQM provided all necessary tools, consumables and standards for MCH testing
Facilitate dissemination workshop for identified stakeholders about findings on CSMs			Planned for Q3-Q4	Planned for Q4 upon receipt of final data that is ongoing	Once final confirmed results are available, a workshop will be planned
Guinea	L El Hadri				
Build the capacity of the National Quality Control Laboratory (LNQCM)					
Assist LNCQM with plans and guidance to remodel and renovate the chemistry lab area and install one AC unit and one generator.			PQM conducted an initial assessment of the country's QA/QC capabilities in January. Currently awaiting approval from the Mission on proposed activities.		
Procure and deliver one Minilab [®] to the lab					
Provide lab supplies and reagents needed to conduct hands-on Minilab [®] and basic tests training of selected medicines				One Minilab procured and delivered to the lab	
Assist the lab staff during the testing of samples collected for the survey				Completed	
Assist the lab with reporting of Minilab [®]				Planned for Q4	Postponed due to Ebola outbreak

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
and compendial data obtained from the field					
Strengthen the capacity of the Drug Regulatory Authority (DNPL)					
Support DNLP by reviewing the current version of the National Pharmaceutical Policy (NPP) and new registration directives				Planned for Q4	Postponed due to Ebola outbreak
Organize three-day meeting with PQM consultant to present the revised NPP to key stakeholders; finalize it					Postponed due to Ebola outbreak
Present final copy to MSHP for its homologation					Postponed due to Ebola outbreak
Assess the existing registration system at DNPL; identify gaps					Postponed due to Ebola outbreak
Provide TA to address identified gaps in order to improve the structure and functions of the registration department					Postponed due to Ebola outbreak
Strengthen the quality control of medicines by initiating the establishment of a Medicines Quality Monitoring program (MQM) and promote taking regulatory actions					
Organize a meeting w/ key stakeholders to discuss the sampling and testing of selected medicines circulating in Guinea				Planned for Q4	Postponed due to Ebola outbreak
Identify survey team and select source of sample collection from public, private, and					Postponed due to Ebola outbreak

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
informal sectors					
Train survey team in sampling strategies and lab team in testing selected medicines using Minilab® tests					Postponed due to Ebola outbreak
Collect samples from selected outlets					Postponed due to Ebola outbreak
Supervise testing at LNCQM					Postponed due to Ebola outbreak
Provide the LNCQM with ref standards and reagents to conduct Minilab® tests on collected samples					Postponed due to Ebola outbreak
Conduct confirmatory testing at CePAT					Postponed due to Ebola outbreak
Share results of final report with relevant partners, country MOH					Postponed due to Ebola outbreak
Promote enforcement actions to be taken by DNPL based on the survey data					Postponed due to Ebola outbreak
Kenya	L El Hadri				
Continue strengthening medicines quality monitoring of antimalarials at existing sentinel sites and expand to new sites					
Conduct one round of sampling and testing of AMs at 11 sites		Planned for Q3		MQM sub-award completed and sent to PPB; sampling will start in Q4	One round of MQM activities completed
– Procure Minilabs and establish 6 new sites		Minilabs procured and delivered to the sites			
Conduct training on Minilab basic tests, sampling strategies and reporting MQM data		Planned for Q3		Training on Minilab tests, sampling strategies, and reporting provided to 22 staff from the 11 sites	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct M&E visits to three sentinel sites and one port of entry				Planned for Q4	Completed
Continue promoting regulatory actions by sharing MQM data with stakeholders and by raising awareness					
Promote efforts to support enforcement actions by PPB based on MQM data				Planned for Q4	5 regulatory actions taken by PPB
Raise awareness about quality and share data w/PPB, DOMC, and other stakeholders					Report on findings submitted to stakeholders
Continue strengthening capacity of the NQCL and assist the lab toward improving its QMS and toward reaching ISO 17025 accreditation					
Improve technical capacity of NQCL staff on QMS				Lab visit conducted and review of QMS activities completed	
– Facilitate participation of NQCL in NOMCOL activities/meetings			One lab staff participated in the NOMCOL meeting		
Prepare lab to be audited by SANAS		Assisted the lab with resubmission of SANAS forms	SANAS audit scheduled for July 2014	SANAS audit completed	
– Review required documentation			Progress report reviewed		
– Facilitate audit by SANAS and follow up report findings			Planned for Q3 and Q4	Follow up on audit conducted; report on findings will be submitted in Q4	Report on the mock audit findings submitted to NQCL
– Review CAPA actions and facilitate accreditation visit			Planned for Q3 and Q4	CAPAs reviewed	
Liberia	L El Hadri				
Continue building the capacity of the LMHRA Quality Control Laboratory					
Provide lab supplies and reagents needed to		Provided lab supplies and reagents needed to			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
complete R4 of MQM and to conduct R5		complete round 4.			
Assess the lab's QMS and technical capacity			LMHRA is preparing the lab for the upcoming QMS assessment planned for Q3	QMS assessment will be conducted in Q4	QMS audit visit was postponed due to Ebola outbreak
Establish an action plan to prepare the lab for ISO 1705 accreditation			Activities planned for Q3	Planned for Q4	Postponed due to Ebola outbreak
Provide one-year maintenance contract for lab equipment in collaboration w/LMHRA			Maintenance contract provided to the lab		
Train lab staff in preventive maintenance and troubleshooting of major lab equipment			All 3 designated lab staff trained in preventive maintenance		
Support Lab participation in the NOMCOL-Africa		The LMHRA MD and the QC manager participated in the NOMCOL meeting and training in Ghana			
Continue strengthening LMHRA's regulatory capacity					
Establish database for inspectors to control meds entering the country and circulating in the Liberian market		Database established	New virtual inspection tool established and all 15 inspectors and registration staff trained in its use		
Assist strengthening PV system – modifying reporting forms for new software and training on data entry/analysis			New pharmacovigilance electronic form established and LMHRA staff trained on data entry and analysis		
Strengthen monitoring the quality of antimalarial medicines at four sentinel sites and promote regulatory actions					
Complete R4 sampling & testing at Bomi site		Sampling and testing at the site completed			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Select two new sampling sites for R5 w/LMHRA & NMCP			2 new sites selected and added to MQM round 5		
Facilitate R5 sampling & testing following new protocol at four sites			Planned for Q3	Will be conducted in Q4	Postponed due to Ebola outbreak
Conduct M&E visits, review data, review final report					Postponed due to Ebola outbreak
Draft and share reports with stakeholders			Planned for Q3 or Q4	Report of round 4 completed and will be disseminated at round table meeting in Q4	Dissemination meeting postponed due to Ebola outbreak
Promote LMHRA taking enforcement actions based on MQM data			Planned for Q3 or Q4	LMHRA took more than 10 regulatory actions on non-conforming medicines	
Raise public awareness by filming regulatory actions (confiscation of failed samples in the market) for media			Planned for Q3 or Q4	Will be conducted in Q4	Postponed due to Ebola outbreak
Mali	M Hajjou				
Strengthen the capacity of the National Laboratory of Health (LNS) to attain ISO 17025 accreditation					
Strengthen technical capacity					
– Procure needed lab supplies & equipment				A new detector for the HPLC system was procured and delivered to the lab A qualification kit for the UV-Vis spectrophotometer was procured and used to qualify two spectrophotometers Adequate reagents for	The new HPLC detector was installed Two sets of weight standards, one for metrology and one for routine calibration of balances, were procured and delivered to LNS

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Karl Fischer titration were procured	
– Provide TA for servicing, maintaining equipment					
– Train laboratory staff			8 lab staff were trained in UV-Vis including calibration/qualification of spectrophotometer and identification and assay tests using UV-Vis according to USP and BP	2 staff received training in Karl Fischer titration, and 2 trainers received refresher training in UV-Vis spectrophotometer qualification, allowing them to qualify two instruments	
Strengthen QMS by developing SOPs, a training program, internal audit system, and raising managers' QA awareness		22 SOPs finalized	Refresher training in Good Documentation Practices provided to 8 LNS staff Work flow of QC lab at LNS reviewed and recommendations provided to develop necessary SOPs	The implementation plan to help the QC lab attain ISO 17025/WHO prequalification was developed and revised, and is under review	LNS management approved the implementation plan Lab documentation was reviewed and new SOPs drafted for work flow and qualification of UV-Vis spectrophotometers QA developed files for each piece of lab equipment; inventory of lab equipment and supplies was carried out
Monitor and evaluate training				Follow-up practices of analytical methods included in previous training were supervised by the head of the QC lab	PQM reviewed lab staff performance and the lab report on inter-laboratory testing
Support participation in NOMCoL-Africa		Facilitated the participation of the LNS Director General in the third annual meeting of			LNS completed inter-laboratory testing and submitted report. PQM reviewed the report and

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		NOMCoL. The DG is currently the Chairperson of the Network.			provided comments and recommendations to the lab. LNS has shown improvement in conducting testing, documenting lab work, and reporting test results
Support pre- and post-marketing quality monitoring of antimalarial medicines					
Conduct MQM of antimalarial meds				In process	
– Revise the MQM protocol		MQM draft protocol developed and shared with local partners for feedback	Workshop organized to revise MQM protocol in collaboration with local partners including LNS the medicine regulatory authority (DPM), the malaria control program (PNLP), the tuberculosis control program (PNLT), the pharmacovigilance center, and the national directorate of health (DNS)		
– Prepare and facilitate one round of sampling & testing			Existing Minilabs replenished. 3 Minilabs procured for the sentinel sites in Gao, Timbuktu, and the new sentinel site in Kidal. 19 staff from Regional Directorates of Health, LNS, PNLP, and PNLT received training in sampling and screening of medicines using Minilabs	Resources to start sampling and testing of antimalarial medicines were provided to LNS 80 samples were collected in the district of Bamako, and 48 samples were collected at the Koulikoro sentinel site. Minilab screening was completed on all samples collected Refresher training and	Sampling and testing of antimalarials at Bamako and Koulikoro completed. The completion of sampling and testing and the other sites is scheduled for mid-Dec 2014

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				sampling plans for the remaining sentinel sites have been developed	
Monitor and evaluate MQM activities w/supervisory visits and review/validate data				Raw data from Minilab testing as well as sampling documentation were reviewed; doubtful and failed samples were verified	PQM consultant will conduct a supervisory visit to Ségou sentinel site in Oct 2014, then the other sites through mid-Dec
Raise awareness of counterfeit and substandard medicines and promote corrective actions				The issue of taking corrective actions was discussed with the head of the Directorate of Pharmacy and Medicine (DPM). The DPM is developing internal procedures that include responding with corrective actions when substandard or counterfeit medicines are found	LNS will communicate the results of MQM to DPM
Support coordination of PQM activities in the country					
Hire a locally-based consultant		Consultant position description drafted	Consultant position was advertised in the local newspaper, and a candidate has been selected; the hiring process is underway	The consultant was hired and has started working closely with local partners	PQM consultant has been actively involved in planning and facilitating/carrying out PQM activities
Mozambique	R. Okafor				
Strengthen the capacity of the National Laboratory for Medicines Quality Control (LNCQM)					
Strengthen quality management capacity by training the staff		New QA staff appointed; assessed personnel to properly plan for training	Training planned in May for new QMS	DF director asked PQM to hold off on training until 2 new staff begin working	The new staff to be designated as the QA manager has still not arrived
Strengthen analytical capacity of LNCQM		Trained staff in December on key QC tests: HPLC –	Training planned in May for new QMS	Training on Uniformity of Dosage Units and how to use USP and other	Training on processing HPLC data provided; additionally, PQM helped

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		calculation and running, UV/Vis, and KF Also trained 2 new staff on effectively using pharmacopeias		pharmacopeia was conducted	the lab resolve and complete the NOMCOL ILT test
Assist LNCQM to refine strategic plan for ISO accreditation/WHO PQ		Discussed changes and delays to ISO accreditation due to recent staff changes with director of DF	Presented the discussed plan to director of DF; pending translation service approval to forward translated document	A refined roadmap to accreditation was provided to DF and LNCQM management as well as USAID; it was translated into Portuguese	Progress is slow due to a lack of qualified personnel, committed involvement, and clear understanding from LNCQM management
Strengthen the capacity of Departamento Farmacêutico (DF)					
Assist DF and encourage to take regulatory actions		Discussed the decree for DF and CMAM that will allow autonomy to take regulatory actions; more discussion needed pending response from MOH		This issue was revisited with the new CMAM director during a meeting among USAID, PQM, CMAM, and other partners to discuss PQM activities in the country; future meetings will be held to discuss assistance with regulatory actions	During the Aug 2014 trip, USAID, PQM, and DF/LNCQM discussed the lack of action, and USAID wants PQM to prepare a presentation that could be used with higher officials at meetings with USAID
Encourage and train DF staff at port directorate			Planned for Q3	3 Minilabs were ordered for the 3 ports chosen by USAID, PQM, and DF; training at the new sites will take place in August.	Training took place at LNCQM in Aug; provincial staff were trained along with CMAM staff
Encourage DF to dedicate funds for LNCQM sustainability		Discussions held with DF and key staff during visit in December; provided technical assistance to MOH staff on procurement list of items/regents and consumables	Planned for Q3	MOH and Permanent Secretary have promised to set aside funds to support the lab	PQM discussed the lab taking ownership of some activities, like taking ownership of bringing the metrology institute on board to calibrate balances
Support the MQM program by expansion into the ports of entry					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Extend MQM to 2 new sites; conduct 2 rounds MQM sampling, testing at 3 additional sites			MQM delayed due to contractual delays; planned for Q3-Q4	Contractual delays resulted in improperly collected MQM samples (not enough funds to purchase medicines); results nonetheless have been submitted for the FY13 rounds. FY 14 funds were transferred in Jun	3 main ports were added as MQM sentinel sites, and 3 Minilabs were provided; LNCQM and DF staff will be responsible for taking the Minilabs to the port for screening; The Minilabs will be housed at LNCQM as agreed by the DF director
Supply new sites; train provincial staff and DF inspectors			MQM delayed due to contractual delays; planned for Q3-Q4	Training planned for Aug at LNCQM	Training took place at LNCQM in Aug; 24 provincial staff were trained
Support DF efforts on enforcement actions based on MQM data			MQM delayed due to contractual delays; planned for Q3-Q4	In progress, pending MQM results	In progress, pending MQM results
Nigeria	M. Hajjou (Malaria); L. Evans (MCH)				
Monitor the quality of antimalarial and maternal child health medicines					
Conduct two rounds of sampling and testing of antimalarial meds		Budget provided to the National Malaria Control Program for conducting one round of MQM activities	Sampling protocol drafted, revised, and finalized Sampling conducted at all sentinel sites; testing of samples is underway	Completed testing of all antimalarial samples.	
Conduct QC testing of each batch of zinc sulfate tablets procured by USAID from Chi Pharmaceutical			PQM received 8 batches of zinc sulfate tablets from CHI Pharmaceutical procured by USAID Deliver. The batches are to undergo QC analysis prior to release by DELIVER.	PQM completed QC analysis of 8 batches of zinc sulfate tablets from CHI Pharmaceutical and provided the results to DELIVER	
Promote enforcement actions				Report on MQM activities was drafted by NAFDAC central laboratory	PQM reviewed data and provided comments and recommendations to

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				management; it is under review by NAFDAC headquarters	NAFDAC
Monitor MQM activities w/NAFDAC & NMCP			NAFDAC is supervising sample testing at NAFDAC labs; NMCP and Supply Chain Management are monitoring the implementation of MQM activities		PQM will review the implementation of the first round of MQM with NAFDAC and NMCP by Nov 2014 and draw lessons for improving the implementation of the activities
Strengthen the regulatory capacity of NAFDAC					
Support training of NAFDAC staff in GMP and dossier evaluation					
Prepare the QC Lab for WHO Prequalification					
– Strengthen analytical capacity			Trained NAFDAC lab staff in proper use of pharmacopeia and HPLC	Procured lab supplies including consumables and devices to monitor the lab environment. Trained 25 NAFDAC lab staff in the following: <ul style="list-style-type: none"> • Dissolution: Theory and Best Practices • UV-Vis Absorption Spectrophotometry • Loss on Drying • Disintegration • Uniformity of Dosage Units 	Laboratory supplies including columns for HPLC, tools to monitor lab environment, and calibration reagents were procured and delivered to the NAFDAC lab 23 NAFDAC lab staff received training in good volumetric practices, good weighing practices, HPLC, and HPLC troubleshooting Monitoring and evaluation of training in HPLC, pH, proper use of pharmacopeial standard documents, Dissolution, and Karl Fischer titration were conducted by directly

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					observing lab staff carry out these tests. PQM provided recommendations and corrections to the lab staff onsite. Lab staff were also quizzed on the training they received in the past and recommendations and observations were shared with the trainees as well as the QA unit
– Strengthen QMS		Drafted implementation plan for NAFDAC lab to attain WHO PQ/ISO 17025 accreditation	Trained NAFDAC lab staff in understanding ISO 17025, internal audit process and methods, reporting and reviewing test results, and corrective and preventive actions	<p>Developed 9 SOPs and reviewed quality manual; NAFDAC lab participated in proficiency testing for Karl Fischer titration, Loss on Drying, UV spectrophotometry, pH, and HPLC. The lab also participated in NOMCoL inter-laboratory testing and submitted a report</p> <p>NAFDAC lab implemented corrective action plan in the following areas:</p> <ul style="list-style-type: none"> • Safety and good housekeeping • Handling of test items • Document control • Personnel training and training records • Monitoring of environment • Corrective actions and preventive actions 	Lab staff received training in quality management systems

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				<ul style="list-style-type: none"> Reporting and evaluation of tests results 	
Support NMCP in finalizing the quality assurance policy for its medicines and diagnostics					
Assist NMCP in finalizing draft QAP					QAP draft was reviewed, and it was decided to develop a new draft. Documentation was gathered and a new outline of the QAP was developed. Development of the new PQA draft is underway and will be completed by Oct 2014
Assist NMCP in drafting & reviewing procedures to implement QAP					
Build capacity in GMP of selected local manufacturers of zinc sulfate, ORS, chlorhexidine, and amoxicillin commodities for global and local supply					
Provide TA to selected local mfrs of CHX by conducting gap analysis, technology transfer, and formulation activities		Conducted a gap analysis of Drugfield's CHX manufacturing line for compliance with cGMP.	<p>Provided a detailed report of observations from the gap analysis to the manufacturer who developed a CAPA plan on which PQM provided feedback. By the end of the quarter, 60% of the CAPAs were closed by the manufacturer.</p> <p>PQM analyzed samples of the first batch of CHX gel developed by Drugfield.</p> <p>In March, Drugfield received NAFDAC approval to market CHX</p>	<p>PQM participated in the Meeting of the Informal Network of Chlorhexidine Gel Manufacturers in Abuja. The objectives of the meeting were to:</p> <ul style="list-style-type: none"> Exchange updates on Chlorhexidine 4% Address challenges from local manufacturers on progress made regarding gel production Provide a forum for private sector, policy makers, ministries and departments, donor agencies, and others 	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			gel.	concerned with policy and barriers to local production and use of Chlorhexidine 4% gel	
Provide support to CHI ORS mfg to enable procurement by local orgs and USAID					CHI and PQM agreed to re-schedule the pre-procurement assessment for FY15 Q1.
Support add'l local mfrs of zinc sulfate tablets			PQM provided TA to Swipha (sourcing of API and QC services for API and excipients) and Emzor (product development)	PQM visited 2 zinc sulfate tablet manufacturing facilities that are under construction and provided layout recommendations to ensure GMP compliance. Pilot batches were evaluated by physical and visual inspection and technical assistance was given to improve the physical properties of the tablets	
Support add'l local mfrs of ORS				PQM visited one ORS manufacturing facility that is under construction and provided layout recommendations to ensure GMP compliance	
Issue EOI w/NAFDAC to identify mfrs of amoxicillin dispersible tablets		EOI issued in collaboration with NAFDAC and 3 Nigerian manufacturers (Daily Needs, Europharm, and Emzor) responded. PQM visited Daily Needs to determine if they had the infrastructure and			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		capacity to produce the product under GMP.			
Conduct GMP baseline assessments of select mfrs of amoxicillin dispersible tablets					PQM determined that Daily Needs was not ready for the assessment as it was still putting key systems in place. An assessment has been tentatively scheduled for FY15 Q1.
Support one+ mfrs of amoxicillin dispersible tablets to develop for local procurement			PQM began providing TA to Daily Needs by providing API sources with certificates of suitability and product information required by UNICEF.	Amoxicillin manufacturers were invited to the CHX informal network meeting to discuss establishing a group for amoxicillin manufacturers. PQM presented its role and the type of TA it can provide. PQM met with JSI-TSHIP to discuss the strategic priorities and next steps for the informal network of amoxicillin manufacturers	The PQM in-country consultant performed a rapid assessment of Nemel Pharmaceuticals to gauge their readiness for the manufacture of amoxicillin. PQM continued to provide TA to Daily Needs in helping them address issues raised during the NAFDAC audit. PQM was able to obtain UN Commission funding through WHO in Nigeria. With this, PQM was able to provide support for training on the QC analysis of amoxicillin DT. Participants from 4 manufacturers participated in the week-long training at CePAT.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Senegal		L El Hadri			
Continue strengthening the capacity of LNCM and prepare the lab for TUNAC ISO 17025 audit					
Continue improving technical capacity of LNCM staff to conduct testing and improve managerial skills		QMS training conducted at CePAT			
– Facilitate participation in NOMCoL IPT				Completed	
– Provide TA, supplies for IPT and advise on improvements		Supplies provided for ITP testing		Completed	
– Support two senior LNCM staff to take part in NOMCoL trainings at CePAT		2 senior lab staff attended the NOMCOL training at CePAT			
– Provide quotes, specs for new HPLC; provide 1-year maintenance contract; facilitate delivery of unit and reagents			Provided quote and specifications for HPLC to be procured by LNCM		
Prepare the lab for TUNAC ISO audit			Planned for Q3	Documents prepared and reviewed	
– Provide TA prior to LNCM application					Waiting for the lab to get the new HPLC unit as it is part of the lab scope of accreditation
– Review all required documents and forms			In progress	Ongoing	Completed
– Conduct mock audit and report finding, recommend how to address CAPAs			Planned for Q3	Completed	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Strengthen the capacity of DPM and support enforcement of its regulatory actions					
Organize workshop for DPM and customs on enforcing regulations					Communication ongoing with the DPM director
Assist LNCM to prepare additional SOPs		Provided SOP templates to the lab		SOPs reviewed	
ASIA					
RDMA Mekong Malaria S. Phanouvong					
Continue to strengthen the post-marketing surveillance capacity of Laos FDD and BFDI, Vietnam DAV, and select authorities of Burma and Thailand at main trade cities and border areas between countries and checkpoints by maintaining MQM and collecting data to support enforcement against use of oral artemisinin-derivative monotherapies.					
Collect samples of AMLs and suspect ABTs in targeted areas; Collect info on availability of oral artemisinin AML monotherapies; report to all relevant agencies		<p>PQM continued to support the collection of samples and completion of analyses for the Comparative Study. Sample collection has finished in Laos, Vietnam, and Cambodia, and is ongoing in Thailand.</p> <p>Performed data analysis using the MQDB and recent Cambodia and Thai data (not yet in MQDB) to create a flyer for RDMA/PMI entitled Highlights of the Quality of Medicines Collected and Tested in the Greater Mekong Sub-region 2005-2012</p>	Samples were not collected during this reporting period.	<p>Analysis of samples collected in Thailand under GFATM, with technical support from PQM, indicated the presence of artesunate monotherapies. Data collected in Laos is awaiting analysis, but monotherapies were not identified.</p> <p>Data analysis in support of the regional assessment of poor quality medicines has been prepared for a journal submission.</p>	<p>A technical report on the survey of the quality of antimalarials in 22 provinces in Thailand under GFATM in collaboration with Kenan Asia, BVBD, and BDN completed; dissemination is underway. Thai FDA and BVBD will be taking action on failed samples of chloroquine, quinine, primaquine, mefloquine and artesunate tablets.</p> <p>Data collected in Laos as part of the comparative study identified illegal injectable artemether in one private pharmacy in northern Laos. Additional investigations and inspections are underway.</p> <p>Submitted article on global prevalence of poor</p>

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					quality medicines (includes the most recent findings in Laos and Thailand) to American Journal of Tropical Medicine and Hygiene; publication is schedule for FY15 Q1
Purchase and replenish essential Minilab [®] / QC lab supplies to maintain MQM and confirmatory analyses at the Laos FDQCC and Vietnam NIDQC and HIDQC.		PQM provided some 100 reference standards and products to FDQCC; will be distributed to the sentinel sites for MQM	Taking inventory and gathering information from the countries.	Laos FDQCC, NIDQC, and HIDQC have received necessary RS, and FDQCC has ordered and received additional Minilab supplies	No further action this quarter.
Conduct 3-4 supervisory / M&E visits to select sites with MRA, National QC Lab staff and/or NMCP		Site visits were carried out in Cambodia, Vietnam, Laos, and Burma	Site visits are in the planning stages for Thailand and later in Burma. Site visit carried out in Vietnam to Binh Phuoc province (jointly with USAID HQ and RDMA)	Site visits in Thailand were postponed due to political unrest. Visits in other countries were held as planned and additional visits by PQM HQ staff and USAID/RDMA were organized in Vietnam	Laos makes limited sample collection visits due to lack of budget, so the only visits conducted this year were in Q1. Two sentinel site visits took place in Burma by the PQM consultant and DFDA. In Cambodia, seven site visits were made by PQM and DDF.
Analyze data; Laos, Vietnam and PQM produce end-of-FY reports. Burma, Cambodia, Thailand will use their own funding.			Planned for Q4	Working with Laos FDD to complete financial and technical reports	Financial and technical reports completed for Laos. Technical report completed for Thailand on GFATM support project. Cambodia and Burma reports are in final stages.
Continue to strengthen the capacity of the Laos FDQCC toward ISO 17025 accreditation, and of Chulalongkorn University Pharmaceutical Technology Service Center (PTSC) toward WHO Prequalification for reliable test results					
Continue to work with FDQCC management		PQM has been working with BDN to identify an	FDQCC submitted a revised QM and SOPs	Results from March internal review not yet	FDQCC working on translation of QM and

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
on road map and goal of submitting appl. by mid-2014. PQM will assist in reviewing QM and SOPs, advise which accrediting body FDQCC should apply, and help the FDQCC respond to any queries.		accreditation body and review the Quality Manuals (QM) and other documents from FDQCC. PQM attended the ISO 17025 accreditation ceremony in November 2013 where the Laos FDQCC received accreditation for two products (amoxicillin and paracetamol).	to PQM for review	received due to staff shortages at FDQCC Inter-laboratory testing samples sent to FDQCC for testing in Q4 PQM QMS team continued to review the FDQCC's Quality Manual and SOP documents	SOPs. Increasing recognition by other agencies (BFDI/FDD) of the need for ISO accreditation and for increased funding for HR and equipment. Staff shortages continue to limit the lab.
PQM will continue to support the Chula PTSC lab toward WHO PQ by the end of 2014 so that it can increase its services in training of advanced methods.		Initial assessment visit was completed and recommendations provided to PTSC	PQM is providing assistance to the PTSC toward WHO PQ; full assessment will occur in Q3.	Assessments in Thailand postponed due to political unrest. Meetings held with Chula in May indicate a high degree of interest in training and testing service provision for the region	Full assessment of the PTSC by WHO PQ is rescheduled to Dec 2014 and a new agreement of collaboration is being drafted.
Support in-country and inter-country efforts and coordination among GMS countries for cooperation and enforcement through BREMERE, WHO SSFFC medical products working group, INTERPOL's Storm Enforcement Network, and ASEAN Post-marketing Alert System (PMAS).					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all SCM cases among enforcement agencies in Laos and Vietnam.		The new regional PQM consultant participated in Minilab training in Myanmar in December 2013 to increase coordination across the region. In December, meetings were held in Thailand with BDN and FDA focal points to review progress for the year and provide an	In addition to all GMS countries nominating two representatives, the Philippines FDA also nominated 2 representatives One antimalarial product (Quinine Sulphate tablet, batch no. 1-QL724, labeled to be manufactured by Macleods Pharmaceuticals, India,	Testing results presented to Thai authorities in May indicate ongoing quality issues. Release of information to BREMERE has not yet been authorized. Discussion on potential collaboration between PQM and ASEAN working groups on pharmaceuticals continued.	Illegal artemether sample found in Laos will be reported to BREMERE when approved. Reducing political resistance to reporting would improve information exchange. Support being provided to prepare funding requests from GF that will enhance inspection response and information exchange through the BREMERE

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		<p>introduction to the regional PQM consultant. Joint site visits with USAID RDMA and local government partners are planned for Q2.</p> <p>In October, BREMERE representatives from national testing labs were trained on Bioequivalence/Bioavailability testing methods. In November 2013, Thailand provided the final nominees needed to complete the BREMERE team.</p>	<p>had no active ingredient, and found in Ghana, Ethiopia, and Kenya) was investigated through BREMERE. The outcome of the investigation was that this product has not been found in the GMS countries.</p>	<p>A concept note on 'Potential Areas of PQM Technical Assistance to Strengthen the Technical and Regulatory Capacity of ASEAN Countries' was developed and submitted to AOR team</p>	<p>network.</p>
<p>Support inter-country / regional BREMERE, ASEAN PMAS, and INTERPOL cases through timely sharing of information and data, and joint investigation and enforcement.</p>		<p>Ongoing information sharing on product samples collected and tested among in-country partners</p>	<p>PQM held a meeting with the USFDA, the WHO SSFFC responsible team, and USAID Washington at USP HQ to discuss complementing each other's' efforts in combating CSMs at regional & international levels. The meeting resulted in concrete follow up action items.</p>	<p>Presented Thai data to RDMA under limited release due to lack of approval for dissemination</p>	<p>Regional BREMERE operation and leadership needs more political support in each country for timely information sharing which has often been hindered by heavy bureaucratic steps and slow authorization by the MRAs. In 2013-2014, only four cases of antimalarial samples were shared and investigated via BREMERE.</p> <p>Approval for dissemination still has not been received from Thai authorities; the</p>

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					comparative study results of failed samples in Vietnam have not been approved for dissemination either.
Increase the availability of quality-assured AMLs by improving inspections in supply and distribution chains, supporting selected manufacturing facilities to produce quality ACTs, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of CSMs in the GMS.					
Improve inspector practices in supply and distribution chains with training of trainers and hands-on inspection exercises to support oral monotherapy ban.				Planned for Q4	Materials for use in training and SOP development for inspections provided to BFDI contacts and FDD focal points. Continued work planned to develop appropriate training SOPs suited to the Lao context.
Strengthen Laos pharmacy practices through national/local training of operators in targeted containment priority areas and help implement the oral monotherapy ban.				IEC study in Laos indicates high awareness of the general danger of counterfeit medicines but limited understanding of the concept of resistance.	Dissemination of the results of the comparative study and IEC study planned for FY15 Q1 following report approval.
Conduct initial assessment of dossier and GMP compliance of two potential mfrs in Vietnam to receive TA toward producing ACTs for the region.		Identifying manufacturers in Vietnam in close consultation with local partners	In March, PQM staff and the local consultant held meetings with selected manufacturers of ACTs in Vietnam to explain the WHO PQ process. PQM sent questionnaires to the manufacturers to collect additional information to help in the selection process.	PQM received responses to the manufacturer questionnaire from two manufacturers (SaoKim Pharmaceutical JSC and OPC Pharmaceutical joint-stock company) and PQM GMP Manager paid an initial visit to each of them. Observations with associated remedial actions were provided to the companies.	GMP expert assessed one local manufacturer (Sao Kim Pharmaceutical JSC). Another assessment (for OPC Pharmaceutical JSC) was delayed due to security issues in south Vietnam. This has been postponed to FY15 Q2.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Engage final-year students and faculty members of Laos Univ. of Health Sciences Faculty of Pharmacy in PQM efforts to improve pharmaceutical practices by improving curriculum/participation in relevant pharmacy school forums, scientific meetings, and conferences about medicines quality.			PQM staff and consultant met with the Deputy Dean and two members of the Faculty of Pharmacy to discuss potential involvement of pharmacy students in supporting the MOH/FDD and provincial authorities' efforts in the reduction of poor-quality essential medicines in Laos. The Deputy Dean shared the Pharmacy curricula for PQM to review and provide comments; PQM regional consultant has begun initial review.	Outlines of curricula from Cambodian and Laos universities were received and are under PQM review; additional information will be collected.	Provided "Operational Guide on Improving the Quality of Medicines in Resource-Limited Countries" for Laos and Vietnam. It is hoped that improved training of pharmacists will increase awareness of the need for quality medicines and they will extend the reach of local authorities to support medicines quality; the curriculum was found to be limited in detail on the consequences of CSMs for resistance development.
Participate in/present at meetings and conferences to share the findings and achievements of and challenges to PQM program activities, in national, regional, and international arenas.					
Disseminate publicly data and findings from PQM activities through appropriate means; also present PQM work progress/achievements at conferences and meetings on medicines quality issues.		<p>PQM submitted an editorial to the Bulletin of WHO about MQDB, to be published in the Jan 2014 issue</p> <p>A journal article detailing the success of Cambodia's efforts in reducing counterfeit medicines was written and sent to Cambodian authorities for approval. Publication is expected in Q2.</p> <p>A draft report was</p>	<p>A journal article entitled "Cambodian Ministry of Health Takes Decisive Actions in the Fight against Substandard and Counterfeit Medicines" was published in the Journal of Tropical Medicine and Surgery.</p> <p>The report on a 'Pilot Project on Information, Education, and Communication (IEC) Strategy for combating counterfeit and</p>	<p>Data on SE Asia, including the Mekong Sub-region, was presented at the WPRO Regional Meeting on Regulatory Capacity Strengthening and shared with relevant parties, including PMI and USAID teams in the region.</p> <p>A journal article on global trends in poor quality medicines is being prepared; anticipated publication in</p>	<p>Poster presentation by PQM staff at FIP in Bangkok on MQDB generated awareness and interest in the dataset.</p> <p>Completed submission of journal article "Monitoring the Quality of Medicines: Results from Africa, Asia, and South and Central America to AmJTropMed."</p>

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		Q1	Q2	Q3	Q4
		prepared describing the effects of IEC initiatives in Laos. The report will be finalized in Q2.	substandard medicines in Lao PDR' is being finalized.	AmJTropMedHyg in Q4	
Burma G. Nayyar under leadership of S. Phanouvong					
Strengthen PMS capacity of Burma DFDA and selected authorities, primarily at Malaria Containment Zones/Tiers 1 and 2, border checkpoints with Laos, Thailand, and China, through MQM activities to obtain evidence-based data and reduce oral artemisinin-derivative monotherapies.					
Collect samples of AMLs and suspect ABTs in targeted geographical areas. Collect info on availability of oral artemisinin AML monotherapies; report to all relevant agencies		Training on MQM was given to 34 participants from DFDA, DMR-LM, VBDC and WHO in Dec 2014	Training on MQM given to 28 participants from DFDA in March 2014. Sample collection in 5 sentinel sites and Burma-India border began at the end of March. Field testing will occur at the end of April.	Sample collection and field testing finished in two border areas (Tamu and Muse). Sample collection from 2 sentinel sites (Rakhine and Tanintharyi) conducted in collaboration with CAP-Malaria. Sample collection from another 2 sites (Bago East and Mon) to be conducted by DFDA in Q4. Monotherapies are still found in border areas.	Minilab and confirmatory testing results are available from two border areas. Due to the relocation of the DFDA Nay Pyi Taw laboratory, confirmatory testing is delayed. MQM/PMS activities for sample collection in Bago East and Mon are underway. Confirmatory testing for Rakhine and Tanintharyi is underway.
Purchase and replenish essential Minilab® / QC lab supplies to maintain MQM activities and confirmatory analyses			In Feb 2014, PQM provided 21 essential Minilab supplies to replenish the sentinel sites, as well as some for use in the training discussed above.	Completed	Completed; open communication has been established to see if additional needs exist
Conduct 3-4 supervisory / M&E visits to select sites by PQM consultant(s) with DFDA and VBDC.		Formal clearance requested	Supervisory visit will be conducted on Burma-China border and 3 sentinel sites in Q3	Plan for supervisory visit at Burma-Thailand border and 3-4 sentinel sites in Q4	Activity is pending and will be undertaken in FY15 Q1
Compile and analyze data (country mgmt.			Planned for Q3	Planned for Q4	Results from two border areas are available with

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
team) from sites and results from DFDA QC lab; PQM consolidates data and reports.					failure rates of 23.5% (51 tested, 39 passed, 12 failed). Results from other sentinel sites are still being processed and analyzed. Dissemination plan is being discussed for appropriate action.
Continue to strengthen the capacity of the national quality control laboratory of DFDA in Nay Pyi Taw to comply with basic principles of Good Laboratory Practices and help it conceptualize the ISO 17025 accreditation process.					
Provide essential laboratory equipment and hands on training to DFDA QC Lab staff in Nay Pyi Taw		<p>PQM donated one dissolution tester to the DFDA lab in Nov 2013</p> <p>In addition, PQM donated essential laboratory and personnel safety supplies, reference standards, and reagents to DFDA lab in Nay Pyi Taw to support the trainings conducted in March 2014</p>	<p>PQM donated one Agilent HPLC auto-sampler system to DFDA. The machine was installed in Feb by Agilent.</p> <p>PQM donated two copies of USP-37 NF-32 to DFDA and one copy of USP-37 NF-32 to DMR-LM in Jan 2014</p>	<p>3 site visits to proposed relocation sites of the DFDA Nay Pyi Taw QC laboratory were conducted. Technical suggestions were provided to DFDA. The renovation of the building to house the Pharmaceutical Chemistry lab has started in line with input from PQM.</p>	<p>The renovation of the laboratory has been completed and the lab has relocated. Re-calibration of lab equipment is in progress.</p>
<p>PQM and Chula PTSC will train the lab staff on GLP, QMS, and concept of ISO 17025 accreditation process</p> <p>Provide technical guidance on how to build capacity of the lab in HR, developing technical expertise, equipment specs, etc.</p>		<p>Training on advanced analysis on dissolution property of antimalarials was conducted in Dec 2013. 10 participants from DFDA and 2 from DMR-LM attended.</p>	<p>A workshop on advanced analytical methods using HPLC was conducted in Mar in collaboration with WHO Country Office for Myanmar and Faculty of PTSC. 12 participants from DFDA, 2 from DMR-LM, and 10 observers from DFDA attended.</p>	<p>Completed</p>	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support in-country and inter-country efforts and coordination among GMS countries for cooperation and enforcement through BREMERE, WHO SSFFC medical products working group, INTERPOL's Storm Enforcement Network, and ASEAN Post-marketing Alert System (PMAS).					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all SCM cases among enforcement agencies		<p>The new regional PQM consultant participated in Minilab training in Myanmar in Dec to increase coordination across the region.</p> <p>Two regional trainings were conducted in the Philippines in Sep and Oct. Training in Sep focused on GMP; in Oct, the BREMERE reps from national testing labs were trained on Bioequivalence/Bioavail ability testing methods. In Nov, Thailand provided the final nominees needed to complete the BREMERE team.</p>	Results of the baseline survey in Burma were submitted to the DFDA for action	PQM continued to follow up on engaging DFDA to take action on non-conforming samples found in the baseline survey and hope to share the results with BREMERE focal points in each country	In the national newspaper, DFDA announced the list of illegal medicines that were found on the market during MQM/PMS activities conducted in two border areas
Increase the availability of quality-assured AMLs by improving inspections in supply and distribution chains, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of CSMs in the country.					
Conduct a training workshop for 8-10 DFDA central inspectors and 15-18 township inspectors (in containment Zones/ Tiers 1 and 2) to improve inspection practices in the supply and distribution chains to support the ban on oral monotherapies.		Activity is pending	Training workshop for 28 DFDA central and state/division level FDA staff on PMS and MQM conducted in Nay Pyi Taw in March 2014		Additional training is targeted for this region in FY15 to complete this activity.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Engage faculty and final-year students (50) of a pharmacy school in Yangon to improve pharmaceutical practices in various settings through curriculum/syllabi improvement.				Delay in final review of the curricula of Schools of Pharmacy in Cambodia and Laos that could be used for Burma has resulted in a delay in activity in Burma as well.	Discussions for this activity are underway, and key personnel to provide the syllabi have been engaged at respective schools. This activity will be completed in FY15.
Participate in / present at meetings and conferences to share the findings and achievements of and challenges to PQM program activities, in national, regional, and international arenas.					
PQM or rep from DFDA, VBDC, or Dept. of Medical Research-Lower Myanmar will present PQM's work progress/achievements at conferences and meetings on medicines quality issues.				Results of the baseline survey were shared with relevant partners, including DFDA, PMI, and USAID missions (Burma and RDMA)	Results of MQM/PMS activities were shared on an ongoing basis with relevant partners including PMI, USAID Burma mission and VBDC.
Cambodia E. Yuan					
Continue to support strengthening the Cambodia DDF post-marketing surveillance system at national and local levels by implementing the enhanced medicines quality monitoring to obtain evidence-based data, especially on AMLs, to support enforcement action.					
Collect samples of AMLs and suspect ABTs in targeted geographical areas; collect information on the availability of oral artemisinin AML monotherapies and report to the relevant agencies.		Country study teams organized an orientation and refresher training on testing by TLC/Minilab in Nov for 12 participants from 3 MQM-sites and 3 non-MQM sites Sampling and testing started and is ongoing; confirmatory testing at NHQC is planned for Q2 DDF-MoH prepared Guidelines on Recall of	137 samples including AMLs and 2 ABTs were collected from 6 provinces (3 MQM sites and 3 non-MQM sites). Basic testing by Minilab was conducted; confirmatory testing will be done in Q3 No oral antimalarial monotherapies were found.	Confirmatory testing of 52 samples (selected from total collected samples) is in progress with results expected in Jul. If there are any failures, the IMC Secretariat team will evaluate and take appropriate action.	The confirmatory testing results were issued. One sample failed quality testing: Flamox B.F 500mg (Amoxicillin 500mg), manufactured by Bright Future Pharma Ltd., Cambodia. In Sep, the IMC Secretariat team conducted a meeting to investigate the cause of the failed sample. The team decided to collect 2

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		Pharmaceutical Products; will be submitted to H.E Chou Yin Sim for his approval			additional samples of Flomox B.F 500mg, which are stored at the manufacturer's warehouse, for re-testing. One sample has the same batch number as the failed sample; the other is different. The samples are being tested at NHQC, and the results will be released in Oct 2014.
Purchase and replenish essential Minilab [®] / QC lab supplies to maintain MQM activities and confirmatory analyses.		Supplies were replenished.	Reference tablets and reagents were replenished for 3 sites (Pailin, Battambang, and Mondulhiri) and NHQC	This activity is complete for FY14	This activity is complete for FY14
Conduct 4-5 PQM supervisory / M&E to sites representatives from DDF, NHQC and NCM.		The PQM local consultant joined with representatives of DDF, NHQC, CNM and provincial drug inspectors to conduct inspections in drug outlets within 6 provinces	N/A	Accompanied by DDF-MoH's inspectors, PQM conducted two sentinel site visits to check MQM sampling & testing procedures and replenish materials if needed. Also, certain pharmacies and drug outlets were checked to monitor and enforce good pharmacy practices.	The PQM local consultant traveled to Siem Reap, Battambang, and Kandal provinces to attend the GPP training (for pharmacists and drug sellers) that was conducted by DDF-MoH.
Analyze data and produce end-of-FY technical reports for country and PQM.				Planned for Q4	Analysis is underway; the technical report will be produced when analysis is complete
Continue to strengthen the capacity of National Health Product Quality Control (NHQC) toward compliance with ISO 17025 international standards of performance and practices for reliable test results.					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
PQM QMS specialists will continue to provide TA to support NHQC lab toward achieving ISO 17025 as agreed upon in 2012 road map. This will entail a visit to meet w/NHQC mgmt. to verify progress.				PQM met with NHQC, who stated that NHQC currently lacks the skills to achieve this currently; in addition, moving to the new building created staff shortages and made it difficult to focus on this activity	PQM's program managers and QMS specialists had a conference call with NHQC's new director, technical manager, and QA/QC manager to (1) receive updates on NHQC's new lab construction with projected moving date; (2) be introduced to NHQC's new management team; (3) identify the gaps and needs in NHQC's existing QMS and set action items with timeline toward ISO 17025 accreditation. NHQC is participating in the NOMCOL Asia Pacific ILT program. NHQC Deputy Director, Mr. Tey Sovannarith, issued the testing results of some medicines and received feedback on testing results from Mr. Hariram Ramanathan of GHIP.
Provide technical guidance to the final stage of new lab construction which may include, but not be limited to, positioning, qualifying & calibrating major lab equipment; and determining the training needs of staff.		PQM provided TA in reviewing the list of lab furniture and equipment. Now PQM is waiting for final construction of the NHQC building.		During the move to the new building, there is no need for equipment or instrument installation and calibration	During the move to the new building, there is no need for equipment or instrument installation and calibration

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support in-country and inter-country and regional coordination, cooperation and enforcement through BREMERE to enhance collective action at national and regional levels.					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all CSM cases, emphasizing AMLS, among the IMC members as well the Provincial Sectoral Committee members at the provincial level.		2 drugs inspectors are representatives of Cambodia for communicating with other countries in the regions			Once the testing results of samples collected during the comparative study are finalized in Oct 2014, the MoH will issue an official declaration to take action on the failed sample; the declaration will be disseminated to all relevant parties.
Support inter-country / regional BREMERE, ASEAN PMAS, and INTERPOL cases through timely sharing of information and data, and joint investigation and enforcement.		Continuous communication	Continuous communication	Continuous communication	Continuous communication
Increase the availability of quality-assured AMLs by improving inspections in distribution chains, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of CSMs in Cambodia.					
Conduct a local 3-day training workshop for each of the four provinces, for operators in targeted areas of artemisinin-resistant malaria containment provinces and help implement the ban on monotherapies.				Since there has been no evidence showing the presence of artemisinin monotherapies in Cambodia, the workshop is on hold	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Engage faculty and final-year students of two university Faculty of Pharmacy schools in Phnom Penh to improve pharmaceutical practices in various settings through curriculum/syllabi improvement.		Initial discussions with the university and the faculty of pharmacy were held.		A meeting was held with the new Dean of the University of Pharmacy. The importance of improving the curriculum by adding QA/QC was discussed, and a proposal to develop a plan of action will be further discussed.	PQM met with the Dean of the Pharmacy School of International University (IU) to discuss the steps to improve pharmacy education at IU.
Participate in / present at meetings and conferences to share the findings and achievements of and challenges to PQM program activities, in national, regional, and international arenas.					
PQM or rep from DDF, NHQC, or CNM will present PQM's work progress/achievements at conferences and meetings on medicines quality issues.		<p>PQM supported the Mekong Bio-Pharma conference in Cambodia in Oct for 400 participants.</p> <p>PQM submitted an article "Cambodia Takes Aggressive Action in Fight Against Substandard and Counterfeit Medicines" for publication in the Journal of Tropical Medicine and Surgery.</p>	<p>PQM's local consultant: --attended USAID's workshop on "Introduction to USAID's Legal Regulation, Financial Management and Procurement Policies" in March in Phnom Penh.</p> <p>--met with MSH consultant (Mr. Kov Buntor) for the project "Analysis of the Regulatory Capacity to Assure the Quality of Antimalarial Medicine in Selected Countries of the Great Mekong Sub-region of Asia" to provide information on PQM activities and any help if possible.</p> <p>--met USAID's evaluation team in March to provide information on the CAP-</p>	PQM's local consultant attended GPP training for drug inspectors in May	<p>PQM's local consultant represented PQM at refresher training for drug inspectors on Drug Law and Regulation, and Law Enforcement to Ban Antimalarial Monotherapy in Aug in Kampong Cham province.</p> <p>In Sep, PQM's local consultant attended a dissemination workshop on guidelines of adverse drug reaction monitoring and related matters and on guidelines for recalling pharmaceutical products for import-export pharmaceutical companies, private and public hospitals.</p>

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Malaria project.		
FY13 Activities to be implemented in FY14 with carry-over funds					
Provide technical guidance to the DDF to develop training materials and help deliver a national workshop on QA/QC of AMLs covering GPP, GSDP, and inspections of supply-distribution chains to all DDF and selected provincial inspectors and key pharmacists from artemisinin-resistant containment areas.		DDF-MoH prepared training materials for GPP training and submitted them to PQM for review.	DDF is revising the training materials and budget plan. Training is scheduled for May or Jun 2014.	DDF-MoH received the budget for GPP training. 14 GPP trainings for pharmacists and drug outlet owners will be conducted between Jul-Oct 2014.	DDF/MoH conducted GPP training for drug sellers and pharmacists from 10 provinces in Jul and Sep. There were 695 participants in total.
Continue to provide TA to the NHQC to successfully prepare its national QC lab's QMS toward achieving the ISO17025 accreditation					PQM's QMS team reviewed NHQC's QMS documents and provided feedback.
Indonesia C. Raymond					
Support the quality assurance of antiretroviral medicines used by the HIV program in Indonesia					
Provide support to Kimia Farma to manufacture quality HIV medicines <ul style="list-style-type: none"> – Conduct a GMP audit of mfg facilities – Identify areas that need improvement – Provide TA to strengthen mfg 			Met with Kimia Farma production team to identify areas of cGMP support and potential project startup in Q3 in coordination with the National AIDS program of Indonesia	An initial GMP assessment was conducted at Kimia Farma's (KF) anti-retroviral manufacturing facility, revealing some observations regarding KF's compliance with GMP for FPP. A follow up and plan for CAPA implementation was agreed upon during the	Follow up visit conducted with KF to determine CAPA implementation progress, identify areas in need of support, etc. The CAPA implementation plan for the ARV facility was 75% complete by the end of Q4. The layout of the new facility will be finalized in 2015. KF has been diligent in CAPA

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		Q1	Q2	Q3	Q4
				next 6 months. ARVs manufactured by KF were sampled for testing by the PPOMN National QC lab (sampled by National AIDS Program, BPOM, and PQM). Testing to be completed in Q4 with reports for the NAP and the Global Fund.	implementation to comply with GMP requirements. Discussion with the NAP manager confirmed the policy requirement for Prequalification for manufacturers in Indonesia for the public program. Therefore, KF has proposed a Nevirapine PQ project, with consideration for Duviral (lamivudine/zidovudine FDC) project as well.
Assess QA/QC capacity of [Papua and West Papua (TBD)] including provincial and district warehouses, health facilities and provincial BPOM QC labs				This activity is scheduled for Q4, including assessment and training on MQM, compendial testing of ARVs & TB medicines, and district-level sampling from warehouses in the public sector	This is tentatively scheduled for FY15 Q2
Provide training for central BPOM lab on HIV, STI, & OI medicines sampling & testing				PQM led a team from BPOM, BINFAR, HIV and TB health programs and conducted sampling of first and second line TB medicines and HIV medicines from GFATM (imported) and those paid for by the Indonesian government (locally manufactured). Samples were collected from three central-level warehouses. All participants were	PQM conducted a two-week training at the national QC laboratory of BPOM (PPOMN lab) on advanced compendial analysis of TB and HIV medicines, including a focus on GLP, HPLC and dissolution of nevirapine in addition to 4FDC TB 1 st line medicines. Plans for supporting a workshop on socialization

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		Q1	Q2	Q3	Q4
				trained on sampling and participated in the sampling exercises. Training and testing of these medicines is scheduled for Q4.	of sampling and testing with MOH & BPOM are in place for FY15 Q1 PPOMN was in the process of conducting tests on the samples collected during Q3 with results forthcoming.
Provide training for two provincial BPOM labs on sampling & testing of HIV, STI, OI, and TB meds		Met with National AIDS program manager (MOH) and WHO HIV country team on testing of ARVs at TUV Lab Singapore, discussion on GFATM QA Policy, and planning for implementation of PQM program; received support and agreement from NAP and WHO	Conducted follow-up meeting with the National AIDS Program Management team (MOH) and PQM senior mgmt. and technical advisor on HIV project under PQM support including QC and cGMP activities, along with post-marketing surveillance, etc.	An implementation plan was drafted and agreed upon between BPOM (PPOMN) and PQM, including scheduling for training and assessments at the provincial and district levels. These trainings are tentatively scheduled for Q4 or early FY15 Q1 based on QC staff availability -conducted a site visit together with USAID Washington to San Clin EQ, Caprifarmindo, and the Bandung provincial BBPOM QC laboratory to see project progress	Participants from Medan, Jambi, and Makassar were trained at the PPOMN laboratory on advanced compendial testing, GLP, etc. on nevirapine tablets as discussed above. Plans are to roll out training on sampling and testing with BPOM and MOH during FY15 in selected provincial/district sites.
Scale-up integration of ARVs into the national post-marketing surveillance program			-Conducted follow-up meeting with BPOM and PQM senior mgmt. and technical advisor on HIV project under PQM support including QC and cGMP activities, along with post-marketing surveillance,	Together with BPOM (Deputy 1) and PPOMN National QC lab, PQM identified areas for scale-up in 50 priority districts for the national post-marketing surveillance program. Unanticipated National Govt budget cuts	Conducted PMS workshop, sponsored by WHO and USP in collaboration with BPOM, to disseminate the results of 2 years' of PMS, including ARVs, to the MOH (BINFAR and CDC programs). Results of the

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		Q1	Q2	Q3	Q4
			etc. -participated in meetings on decentralization SOPs for AIDS program coordinated by CHAI, NAP, JSI, WHO	may require additional PQM funds to make up the temporary budget shortfall. A PMS workshop and planning meeting are scheduled for Q4.	workshop included recommendations on drafting SOPs for cooperation on sampling and testing medicines from government-sector facilities and distribution sites. PQM also held meetings with BPOM senior officials to adopt recommendations to scale-up sampling and testing program of medicines in PMS.
Support BPOM to take part in ASEAN QC activities by identifying where BPOM can play a visible regional role		BPOM representatives attended regional ASEAN workshops on GMP and BE (two separate workshops, duration of one week each) held in Manila, Philippines in October	Signed 5-year MOU with BPOM including areas of support for BPOM on GMP and BE inspectors to participate in regional ASEAN-led initiatives and training	One BPOM officer was supported to attend the regional ASEAN-USP Scientific Symposium held in Vietnam; also supported additional training following the symposium.	3 BPOM technical officers were supported to participate in a week-long training in Vietnam on advanced QC of ARVs and were provided an opportunity to learn from the Vietnam NIDQC lab staff (WHO PQ lab)
Continue existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines					
Assessment, CAPA, and dossier compilation for levofloxacin 500mg of Caprifarmindo		GMP team conducted initial site assessment and provided report for CAPA to Sanbe/Caprifarmindo	-Caprifarmindo implemented CAPA and provided closure report on CAPA items; also updated on status of product development and procurement of new API source from Zhejiang Apelo, China which already has CEP; production to scale up during Q3 -comparator products	Caprifarmindo (Sanbe) attended CPhI workshop on WHO PQ and consulted with PQM's GMP team. Additionally, a tentative training plan is being developed at the request of Sanbe as part of the WHO PQ program. Caprifarmindo has changed its API source to Zhejiang Apelo and started their first	PQM staff visited Caprifarmindo to discuss CAPA implementation. CAPA has been completed 100%. Capri is developing levofloxacin 500mg tablets using API from Apelo and comparator products provided by PQM. Capri will finish the formulation phase during FY15 Q1 and will manufacture

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			provided to Sanbe	commercial batch in Q3. The product dossier should be available by Oct. A CAPA plan is being implemented based on the PQM audit. --conducted a site visit together with USAID Washington to San Clin EQ, Caprifarmindo, and the provincial BBPOM QC laboratory to see project progress	stability batches and compile the dossier for WHO PQ. PQM is also supplying additional comparators for their in-vitro dissolution studies and will conduct dossier compilation training in FY15 Q1.
Action plan, CAPA, dossier compilation for levofloxacin 500mg for Zenith Pharmaceutical Laboratories		GMP team conducted initial site assessment and provided report for CAPA to Zenith Pharmaceutical laboratories	CAPA report submitted for review by Zenith to PQM GMP team, comparator products provided to Zenith	A revised CAPA implementation plan and timeline was submitted to PQM; scheduled to submit to WHO PQ by late 2014. PQM met with Zenith, who attended the CPhI WHO PQ workshop, to discuss Levo 500mg.	Zenith Pharmaceuticals has submitted their CAPA implementation report and documentary evidence based on the audit from Q1. PQM will follow up with the CAPA and provide a dossier compilation training on-site in FY15 Q1.
Specialized training for manufacturers under PQM support on WHO PQ, Validation method of analysis for assay of finished product and assay for raw material (using instrumentation and microbiological method), Validation method of analysis for impurity of finished product and impurity of raw material, Validation in Dissolution Test		PQM provided two-day GMP training for 10 national and provincial MRA offices, MOH representatives, and 17 local pharmaceutical manufacturers. This training was conducted on WHO PQ and GMP requirements, and was co-funded through the GFATM HSS grant to BPOM as sub-recipient		PQM conducted a WHO PQ workshop at the CPhI conference, which was attended by manufacturers currently receiving PQM TA, as well as companies from Cambodia, Philippines, and China	Validation training at Sanbe (Bandung), Zenith/Pharos (Semarang), and Kimia/Sandoz/Kalbe (Jakarta) scheduled for FY15 Q1 conducted by PQM QC staff.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Pharmaceutical development					
Provide TA to Phapros on stability studies, dissolution, BE studies, dossier compilation, etc. for 4FDC product		Assisted Phapros to get clearance and approval from BPOM on BE protocol; reviewed initial protocol, started the due diligence process for sub-award to Equilab to conduct BE studies on Phapros 4FDC product -conducted site visit to Phapros Semarang, identified potential new areas of support on amikacin and levofloxacin -helped to identify potential new API source for Ethambutol at Linaria, Thailand -Phapros conducted BE pilot study with 14 subjects at Equilab International on 4FDC product	-Provided feedback on results from BE pilot study that Phapros conducted during Q1 -PQM sr mgmt. and technical advisor met with Phapros to discuss project progress, upcoming BE study, stability study data, and cost-share sub-award for BE study -PQM in the process of drafting and approving FOG sub-award to Equilab to conduct pilot and full BE studies on Phapros 4FDC product -comparator products provided to Phapros -discussion on initiating levofloxacin project with Phapros	-Phapros attended the CPHI workshop on WHO PQ and met with PQM's GMP team to discuss progress on 4FDC product - PQM still in process for fixed price award for BE cost-share support -levofloxacin comparators supplied to Phapros -new potential source for rifampicin API identified and contacted: CKD Bio Corp from South Korea -4 subjects to be reevaluated from pilot BE study -Lupin of India was re-engaged on behalf of Phapros by GDF in an attempt to get an LOA for the APIMF for rifampicin	PQM followed up on additional 4 subjects pilot BE study and provided inputs into re-analysis of outliers; will supply additional comparator products and re-analyze data with BE expert. PQM also exploring new API sources for rifampicin and ethambutol. PQM finalized sub-contract with Equilab to provide BE study support for Phapros. PQM is supplying levofloxacin comparators for the R&D phase of developing levofloxacin 500 mg
Provide TA to Kimia Farma on stability studies, dissolution, BE studies, dossier compilation, etc. for 2FDC product		-Provided reference standards and comparators -provided comments and feedback on stability study data -revised ongoing stability protocols -reviewed and provided comments on facility renovation that will be submitted to BPOM for	-Reviewed BE study protocol and amended according to PQM and WHO comments -appointed Equilab as CRO to conduct BE studies -submitted due diligence documentation to PQM for sub-award consideration for 50% cost share for BE	-New potential source for rifampicin API identified and contacted: CKD Bio Corp from South Korea -impurities reference standards for rifampicin provided to KF -revised BE study protocol review and feedback submitted by PQM - A fixed obligation grant	PQM followed up with KF on CAPA implementation, which will be completed in FY15 Q2. The new facility layout for the manufacturing site was approved by BPOM, and KF has been implementing the CAPA and following up on GMP compliance. PQM is in the process of identifying new rifampicin

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		Q1	Q2	Q3	Q4
		govt approval -reviewed and revised analytical methods verification for 2FDC -in progress on comparative dissolution -submitted BE study protocol for PQM review	studies -discussions on alternative API sourcing for rifampicin from Hebei to another potential source, in discussion with PQM on this -excipients incompatibility study protocol for 2FDC under review by PQM	is being established between PQM and Equilab for the financial contribution to the costs of the BE studies for Phapros 4 FDCs (both pilot and full BE studies)	API sources since CKD Bio Corp from South Korea was too expensive per kilo.
Provide TA to Indofarma on stability studies, dissolution, BE studies, dossier compilation, etc. for 2FDC product		-Design for new production facility finalized and submitted to BPOM for review, pending approval in Q2 -delivered comparator products and reference standards -issues with rif stability data on 4FDC and 2 FDC products submitted for review to PQM, with the need to potentially reformulate -Indofarma also considering changing rif API source from Shenyang to possibly Sandoz Indonesia (CEP) -BE study protocol under development -discussed other potential products for TA: levofloxacin, zinc sulfate, OI medicines	-Indofarma developing BE study protocol and will appoint Equilab as CRO -new facility blueprints approved by BPOM, contracting and construction to begin this year with 2 year completion anticipated	-Management and director structure changes at Indofarma resulted in slow progress during Q3 -moving forward on construction of new production facility, and pilot plant. R&D still working on 2FDC reformulation and API substitution/formulation for BE study - Indofarma requested to take time for building the new facility and working on documentation and system and will inform PQM at a later stage to resume its participation in the WHO PQ process.	Indofarma activities are on hold at the request of their president/director until further notice.
Provide TA to Sandoz Indonesia on stability			Head of Technical Operations and PQM	PQM met with Sandoz during the CPhI	PQM met with Sandoz Indonesia to follow up on

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		Q1	Q2	Q3	Q4
studies, dissolution, BE studies, dossier compilation, etc. for 2FDC pediatric product			point of contact resigned from Sandoz, PQM is awaiting updates on PQ program engagement from replacement and senior management	workshop; some international policies at Sandoz require them to reevaluate the WHO PQ program. It was decided that they would determine a new timeline, since they anticipate having their TB product procured under the JKN universal health coverage	WHO PQ project status. In discussions, it was decided to move forward on possibly applying to WHO through a variation of site of manufacturer since their product with the same formulation in India is already prequalified. At the end of Q4, Sandoz global management was considering the next steps.
Continue to assist two Indonesian Contract Research Organizations (CROs) to enhance their compliance with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) for BA/BE studies on ATB medicines					
Continue to provide TA and support to Equilab International to conduct BE studies under PQM program		-Completed CAPA from van Zyl final audit -completed pilot BE study on Phapros 4FDC product -facility renovation and movement of patient beds to ground floor for better evacuation and emergency access -parent company Dexa Medica purchased building and will be upgrading facilities at Equilab -PQM-sponsored Equilab staff participated in BE workshop conducted by PQM in Manila as part of an ASEAN regional training	-Drafting sub-award to Equilab for cost share of Phapros 4FDC BE study -PQM sr mgmt. met with Equilab to discuss preliminary results on pilot BE study for Phapros -Equilab appointed as CRO for Phapros, Indofarma, and Kimia Farma for conducting their BE studies under the PQ program	-Met with Equilab to follow up on Phapros pilot study, to re-evaluate 4 investigative subjects, and additional requirements for 50% cost-share for Phapros	PQM will be evaluating the additional 4 subjects pilot BE study from the Phapros 4FDC product, supplying comparator products for the full BE study planned for FY15 Q1. The sub-contract for Equilab was finalized in Q4 and will be executed in FY15 Q1.
Continue to provide TA and support to San Clin EQ to conduct BE		-18 CAPAs completed from van Zyl final audit and submitted to PQM	CAPA review conducted	Conducted a site visit together with USAID Washington to San Clin	PQM conducted a follow up site visit to close the CAPA implementation plan

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		Q1	Q2	Q3	Q4
studies under PQM program		at end of Q1 -PQM-sponsored San Clin EQ staff participated in BE workshop conducted by PQM in Manila as part of an ASEAN regional training		EQ, Caprifarmindo, and the provincial BBPOM QC laboratory to see project progress	from the previous audit. The CAPA was acceptable, and San Clin Eq will be considered for BE studies for the PQM-supported PQ projects.
Provide TA to the BPOM National QC lab towards application for WHO PQ by 2015					
NOTE: a five-year MOU between USP and the Head of BPOM was signed in February, ushering in a new phase of the PQM project through 2019					
Build QC capacity of selected BPOM provincial QC labs			Sr PQM mgmt and technical advisors met with new Head of BPOM, Deputies, and new Director of the National Lab to sign 5-year MOU between BPOM and PQM and discuss implementation and scale up of provincial-level assessments, trainings, and equipping	A PQM consultant reviewed the CAPA report with the PPOMN QC lab and responses made by the lab. Major areas where urgent TA is needed were identified, and an implementation plan to address needs has been established. A plan to qualify all Shimadzu equipment (11HPLC, 3GC, 1UV, 1 IFTR), balances, and dissolution testers was made. The plan includes timelines and deliverables for 1 year of activities.	<p>PQM conducted 2-week training on advanced compendial methods of HIV and TB medicines with the national QC lab of BPOM and followed up on the WHO PQ implementation plan. PQM also provided training on GLP and worked with QA management staff on SOPs and laboratory layout and will continue to provide technical assistance under the implementation plan.</p> <p>Equipment qualification service provider was evaluated and will calibrate all lab equipment in FY15 Q1.</p> <p>PQM is considering providing Dionex HPLC equipment for analysis of streptomycin and</p>

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		Q1	Q2	Q3	Q4
					kanamycin to the national QC lab. Meetings with BPOM and MOH to discuss roll-out of provincial/district sampling and testing in FY15.
Assist the health programs (TB, HIV and Malaria) to comply with GFATM QA policy		CoP Met with NAP and NTP and KNCV/TBCare to discuss socialization of QA manual and appropriate protocols for engaging MOH (CDC and BINFAR) and BPOM to scale up sampling and testing of GFATM and non-GFATM products	Sr PQM mgmt. team and technical advisor met with national managers for National AIDS program and National TB program on implementing QA policy and coordination with BPOM -CoP in Indonesia participated in and provided technical inputs into the week-long Global Drug Facility mission to Indonesia, as follow up to JEMM 2013 and recent issues on forecasting for NTP. Discussions on progress for sampling and testing as well as WHO PQ for local manufacturers	PQM has established a testing plan for all TB and HIV medicines collected from the central level. BPOM will start testing medicines for which it has the capacity. PQM will assist the lab with the training, supplies, and equipment needed to test the remainder of the medicines. The plan includes a timeline to complete the testing of all samples	PQM provided 2 week training on compendial analysis of TB and HIV medicines at the national QC laboratory using samples collected from GF and national program sites. Analysis of first tranche of samples is underway with completion anticipated in FY15 Q1 to report to GF.
Support the BPOM QC lab to be an active member in international and regional initiatives under USP, ASEAN and other development partners (WHO PQ, PIC/S, etc.)		4 officials from BPOM's national QC lab received two week training under the visiting scientists program at USP HQ laboratories as a cooperative support between GFATM and PQM		One BPOM officer was supported to attend the regional ASEAN-USP Scientific Symposium held in Vietnam, including additional training following the symposium. Training on ARVs at	3 BPOM technical officers were supported to participate in week-long training in Vietnam on advanced QC of ARVs and were provided an opportunity to learn from the Vietnam NIDQC lab staff (WHO PQ lab).

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		Q1	Q2	Q3	Q4
				<p>Vietnam NIDQC is planned for Q4.</p> <p>The Director of PPOMN QC lab and a staff officer from BPOM attended the Public-Private Partnerships Strategy Workshop at WHO SEARO in India, working with the National TB Program and Persehabatan Hospital</p>	<p>National QC lab (PPOMN) participated in Inter-Laboratory Testing from USP analyzing ciprofloxacin and coartem. Testing is underway with results to be reported in FY15 Q1.</p>
Supply TB medicines reference standards, HPLC columns, USP-NF Pharmacopeial reference books		Reference standards, USP-NF, HPLC columns provided to national QC lab	<p>Additional USP-NF (latest edition), Food Chemicals Codex, and Dietary Supplements documentary standards supplied to BPOM</p> <p>-Technical Assistance Program agreement signed by Deputy Director of BPOM facilitating and increase in supplies in cooperation with PQM funding streams (TB and HIV)</p>	<p>A consignment of RS was procured for PPOMN laboratory to support training and testing for antibiotics, first and second line TB medicines, ARVs, and impurities. Clearance through the diplomatic cargo of the US Embassy was in process at the end of Q3</p>	<p>PQM delivered complete consignment of Reference Standards and materials to the national QC laboratory at BPOM including RS for HIV and TB medicines. USP NF provided to Equilab International.</p>
Continue to support medicines Quality Monitoring (MQM) for ATBs, ARVs, and AMLs, and selected antibiotics at 5 pilot provincial BBPOM sentinel sites and 5 confirmatory sites		<p>All provincial level data had been submitted to BPOM for review</p> <p>-round two currently on hold due to financial matters internal to the government of Indonesia</p>	<p>-PQM still awaiting final report on MQM initial results</p> <p>-planning for additional training, scale up of MQM under HIV, and additional MQM sampling under planning and to be better incorporated into the</p>	<p>A workshop on post-marketing surveillance data and MQM results is planned for Q4</p>	<p>PQM met with the Provincial Directors and Heads of the QC labs of the 5 provincial BBPOM sites to discuss implementation of MQM project using Minilabs.</p> <p>More planning and discussion is underway to</p>

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		Q1	Q2	Q3	Q4
			national PQM system		identify strategies for amending the protocol to prevent overworking QC lab staff and integrating the duties into routine PMS program. In addition, discussions are in progress to identify and define the quantities of program (govt sector) and private medicines to be sampled and tested (proportions, etc.)
Develop collaborative mechanisms and support for disease programs (NTP, NAP), BINFAR, and BPOM to enhance QC capacity in Indonesia					
Participate and provide inputs to activities under People that Deliver, GFATM grants (HIV, TB, and HSS) and other partner activities		-Conducted TDY site visits under the HSS grant activity for warehouse strengthening at the district level, with WHO, MOH, JSI -ongoing monthly meetings with People that Deliver Indonesia --participated in Strategic Management Team meetings under KNCV/TBCare (WHO, MSH, FHI, JSI, MOH, USP PQM, USAID)	-Participated in TDY for PtD's Executive Director for meetings with WHO-WR, USAID, MOH, and other partners -provided inputs into -participated as member of national technical working groups for HSS and TB GF grants -provided inputs into GDF mission -fielded queries from Global Fund Geneva country team managing the Indonesian portfolio -participated in Strategic Management Team meetings under KNCV/TBCare (WHO, MSH, FHI, JSI, MOH, USP PQM, USAID)	-PQM participated in the GF technical working groups, including providing input for continued projects on HSS, HIV, and TB with QA/QC components -met with Global Fund country team from Geneva -participated in TB Care's Strategic Mgmt Team meetings -participated in GF country team assessment for TB and HIV -participated in monthly meetings with BINFAR, WHO, BPOM, JSI, and others	PQM provided input into the concept notes for the new HSS project, the SRAN for HIV, and the concept notes for the TB/HIV grants under the New Funding Mechanism for the GF.
Coordinate with BINFAR on QC-related		-Monthly meetings with SCM team (CHAI, WHO,	-Monthly meetings with SCM team (CHAI, WHO,	-Planning on HIV pilot project in 2 provinces/10	PQM participated in 2 provincial-level planning

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		Q1	Q2	Q3	Q4
activities on supply chain (warehousing, etc.)		JSI, USP PQM, MSH, KNCV/TBCare, MOH) on current issues: decentralization, universal health coverage, etc. and impacts on QC activities -provided inputs into drafting of 3-year PSM strategy document for BINFAR	JSI, USP PQM, MSH, KNCV/TBCare, MOH) -provided QC-aspect inputs into 2 nd line TB medicines warehouse (GFATM) and BINFAR central warehouse during GDF mission	districts under Oblik building in sampling and testing components at district and provincial levels Following coordination meetings convened by PQM, an official letter from the Director General of BINFAR was drafted and disseminated through BINFAR and BPOM which instructs sampling from 100 district warehouses in 33 provinces to be conducted by BPOM with coordination by BINFAR/MOH. This is a major achievement of PQM's advocacy in this area towards better interagency collaboration.	and assessment workshops on SCMs and Drug Quality. PQM is coordinating with BINFAR on the WHO PQ projects with manufacturers as requested by NAP national manager Following the June WHO-USP workshop on dissemination of PMS data from BPOM, PQM is working with BINFAR and WHO to support the establishment of SOP for sampling and testing from public facilities, warehouses, etc. SOP should be finalized in FY15 Q1-2. PQM will continue to work with BINFAR/P2PL on rolling out workshops on sampling guidelines for public sector facilities and implementing provincial and district-level sampling and testing projects in selected provincial and district sites in FY15.
Establish USP PQM office as an officially-registered entity in Indonesia					
Legal Registration and scale-up of hiring staff		-Met with USAID, law firms, and implementing partners to assist in	-Met with USAID, law firms, and implementing partners to assist in	-Negotiated, drafted, and finalized contract with CEO Suite for outsourcing	Continued to follow up with Moores Rowland on tax exemption and registration

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		Q1	Q2	Q3	Q4
		appropriate mechanisms and options for legal registration in Indonesia -drafted SOWs for staffing country office	appropriate mechanisms and options for legal registration in Indonesia -Sr PQM mgmt. held meetings to discuss registration, staffing, and other legal requirements for Indonesia during TDY -engaged with High Street Partners and a local representative of the Baker and MacKenzie law firm to begin process of official registration and approval with Ministry of Foreign Affairs as international NGO in Indonesia	employee contracts until PQM is officially registered with MOFA, Tax Authority, etc. (anticipated by the end of the year) -secured Moores and Rowland as legal firm to perform all registrations on PQM's behalf -amended SOWs for office staff, placed job advertisements, began interviews to identify candidates for at least 4 positions in the PQM Indonesia office	of the PQM project with the MOFA. Provided updated Assistance Agreement amendment and USAID Letter of Appointment of USP PQM under the A.A. Finalized hiring of 4 Indonesia office staff through outsourcing agency CEO Suite (who will convert to USP employees after formal registration with MOFA is approved).
Office expansion		Discussions began on PQM country office staffing needs, developing SOWs, and identifying office space required to accommodate scaled-up staff and program expansion	Began negotiations on increasing office capacity for scaling up and accommodating more staff for the country program with CEO Suite	Offices will expand in Q4	Finalized expansion of offices to accommodate increase in local staff.
Philippines E. Yuan					
Establish and sustain medicines quality monitoring activities					
Continue to support MQM at 8 existing sites by replenishing Minilab [®] supplies, providing needed training, conducting site		Visited CALABARZON in October	Additional sentinel site visits are scheduled to take place in Q3-Q4	Attended PIDS-DOH-PHIC Sharing Seminar in April The MQM data and relevant information on	Replenished Minilab supplies and reagents; Collected expired medicine samples for proper disposal at FDA

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
visits, and updating MQDB. Report progress regularly.				TB medicines have been shared with other implementing partners	Ongoing process of updating MQDB into the new excel format Prepared for the TB DOTS facility visit in National Capital Region. Contacted IMPACT project sites and the City Health Offices involved in the NTP program.
Expand MQM of ATBs to 4 sites: Regions II, IV-B, X, and XII			Planned for Q4		Activity substantially delayed; scheduled for Dec 2014
Strengthen the capacity of the FDA and its QC Lab to enhance the medicine regulatory system in pre- and post-marketing surveillance					
Build capability of CDRR by training new & existing staff to evaluate anti-TB and anti-infective meds		Completed training on USP PQM-ASEAN-Philippines FDA Joint Training Workshop on BA/BE Studies in October		Phil. FDA joined NOMCoL Asia Pacific inter-lab testing in June	Phil. FDA submitted the test results for the NOMCoL Asia Pacific inter-lab testing Maria Lourdes C. Santiago of the Phil. FDA attended the SMREA training at Harvard University.
Provide training opportunity to FDROs to participate in USP's International Training Program (ITP) on BA/BE studies			In preparation stages		Submitted concept note to USP HQ for progressing the training: Part 1: the BA/BE training in the Philippines with the focus on GLP and GCP hands-on. They attendees will be from Malaysia, Indonesia and Philippines regulatory agencies. Part 2: BA/BE CRO facility visit in Kuala Lumpur,

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					Malaysia to conduct the training on the facility inspection BA/BE establishment
Provide training opportunity to FDA scientist to participate in USP's Visiting Scientist Program (VSP) or International Training Program(ITP) on a broad range of topics			Discussing topics and logistics with USP experts/scientists		Activity has been moved to FY15 as advised by USP Labs
Provide technical and professional assistance in QMS to FDA Davao Satellite Laboratory for ISO17025 accreditation			Planned for Q4		After discussions with the FDA chief, it was decided that TA for Davao satellite lab's QMS can be done by FDA's central lab. This activity is discontinued.
Purchase needed lab equipment & reference materials not included in DOH/FDA budgets through USP TAP		Received 2 USP flash drives (single user)	List of equipment for purchase has been submitted for review and approval	Received 1 USP RS for NOMCoL Asia-Pacific inter-lab testing: Cipro Ethylenediamine Analog, Cipro HCL, Artemeter & Lumefantrine	USP Technical Alliance Program was renewed between USP and Phil. FDA. Membership is valid for 1 year. FDA received the following as part of TAP: <ol style="list-style-type: none"> 1. 2014 USP Dictionary Prink (Book) – Qty. 1 2. 2012 USP Dictionary Supplements Compendium (Two Volume Set) – Qty. 2 3. 2014 USP/NF 2nd Supplement Book – Qty. 2 4. 2014 USP37- NF32

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					USB Flash drive single user – Qty. 3 5. 2014 USP37- NF32 sets – Qty. 2 6. USP FCC 8 th Edition Book – Qty. 1 7. 2014 USP/NF 2 nd Supplement Flash drive – Qty. 3 8. 2014 USP37- NF32 Supplement 1 USB Flash drive single user – Qty. 3
Collaborate with NTP and TB Partners on relevant disease control programs					
Provide TA to the DOH-NTP, DOH-NCPAM and TB partners for activities relevant to ATB quality. Provide TA to NTP based on 2014-16 PhilPACT objectives: Tracking and monitoring the TB meds by sampling and testing their quality on retails stores (pharmacies and private clinics)& wholesale supplies chains, hospital and DOTS facilities		Held meetings with implementing partners (IMPACT and SIAPs) on identifying the TA that our partners need and how best to collaborate	Met with NCPAM managers to discuss the activities that PQM can perform. Held workshop on WHO PQ for TB medicines The participants were from ASEAN countries	Organized and conducted a stakeholders discussion in May to solicit feedback from partners to strengthen QA/QC of TB meds in the Philippines	A TB partners meeting with NTP stakeholders and USAID mission was conducted in Manila. All participants agreed that USP/PQM's TA in monitoring and ensuring TB medicines shall be introduced into TB DOTS facilities and to the nation's TB supply chains at certain points.
NCPAM Activity: Baseline survey on the quality of TB drugs in the public and private sectors			Met with NCPAM managers to discuss the activities that PQM can perform		Carried over to FY15 (specific activities or TA with NCPAM needs to be identified)
Provide Technical input from pharmaceutical					Gathered data to be used in the comparative study

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
quality perspective to the current draft DOH administrative order on : securing the availability & affordability of quality-assured essential medicines in the public sector” through the consultation to NCPAM when required					on generic and branded medicines in collaboration with NCPAM: “Quality comparison study between branded and generic versions of the most frequently used, and most expensive medicines in the Philippines.”
Support local manufacturers towards WHO PQ for first- and second-line TB medicines					
Provide GMP TA to local manufacturers toward WHO PQ		Lloyd, Hizon, and Amherst completed the WHO PQ questionnaire and submitted the Expression of Interest for WHO PQ and product evaluation	Workshop held in March regarding TA toward WHO PQ	Assisted PQM GMP audit team in April at Amherst and Hizon laboratories	Activity completed.
Plan and process to recruit two (2) additional consultants (technical and administrative) to strengthen current PQM team in the Philippines to perform assigned activities			Recruiting has begun	Five candidates were interviewed and two candidates were selected. Background and reference checks are underway	The contract for the technical and administrative staff is being drafted.
Provide leadership in promoting global public health and technical excellence ensuring medicines quality and safety through innovations					
Provide the CHDs with CD-3 device to check the quality of doubtful products and train staff on their proper use			Activity will be performed Q3-Q4 to closely discuss and plan with FDA and local pharmaceutical MFRs how to upload the registration information into the device		Activity removed since the CD3 is not available yet in the market; US FDA has been conducting testing on its own schedule

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Vietnam G. Nayyar under leadership of S. Phanouvong					
Provide technical assistance to local production of methadone					
Work with MoH (DAV & VAAC) to determine a selection process of 1-2 methadone manufacturers for technical assistance from PQM		Follow-up the selection process at MoH (DAV & VAAC). MoH's inspection team finished the assessment of the 5 potential manufacturers Vidipha obtained the registration/production license from DAV after piloting bio-batch production	Vidipha won the VAAC tender with an amount of 2300 L methadone 10mg/ml Other 4 manufacturers are procuring a small amount of methadone API (0.5-1 kg) from difference sources (Sanofi, Siegfried) to pilot the bio-batch production for registration with DAV	Vidipha is producing methadone syrup 10mg/ml 2,300 L to supply to VAAC through a tender process	Danapha obtained their local methadone production license from MOH/DAV. Vidipha obtained permission from the MOH to distribute methadone syrup directly to MMT sites in selected provinces (under the DFAT-funded project).PQM plans to discuss with Vidipha to help establish a QA/QC mechanism for their products in the distribution chain
Pursue obtaining an authorization letter to assess GMP of mfrs			DAV& VAAC have been reluctant to issue an authorization letter to PQM to conduct GMP assessment of mfrs	Pending	Pending. Activity has not taken place as the government has not provided the appropriate authorization to engage local manufacturers
Conduct GMP inspection on 1-2 mfrs and recommend how to address deficiencies			Pending official authorization from MOH/DAV and VAAC	Pending	Pending due to above
Provide technical support to the procurement and importation of methadone finished products for VAAC & Ho Chi Minh City PAC					
Support VAAC and HCMC PACs to select high quality methadone products from reliable suppliers		Follow-up with the national VAAC & HCMC tender for 2014 Arranged meetings with	Sent an assessment tool for obtaining relevant information from overseas mfrs of methadone to HCMC	No feedback/update from HCMC PAC and VAAC Vidipha recently obtained MoH approval and is	The HCMC procurement center has submitted the tender plan to the appropriate city authorities for approval

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		VAAC leaders and HCMC PAC to obtain updates and provide technical guidance	<p>PAC and VAAC</p> <p>Follow-up with the VAAC tender. VAAC opened the tender with 2300 L of methadone syrup 10mg/ml with financial support from Ausaid. Vidipha was the winner and delivery of this amount is expected at the end of 2014.</p> <p>US\$0.5 million will be funded from the local government to procure methadone finished product for HCMC PAC.</p>	<p>authorized to distribute their product directly to treatment centers. In Q4, PQM will provide technical advice on maintaining product quality from distribution to the dispensing centers.</p> <p>HCMC confirmed that it will allocate 7.7 million VND (US\$ 363,000) to procure methadone via the city procurement center. Open bidding will be implemented soon.</p>	
Establish a technical support group to support VAAC and HCMC during procurement/import process		Proposed to help review tender documents of VAAC and HCMC PAC regarding product quality aspects		No response from VAAC and HCMC PAC	No response from VAAC and HCMC PAC
Strengthen the capacity of the NIDQC and HCM IDQC quality control labs					
Assess QMS and practices of NIDQC & HCM IDQC labs for WHO PQ readiness; identify aspects needing TA		<p>Follow-up with NIDQC on the upgrade to the microbiological lab. NIDQC receives US\$200K from government to upgrade the micro lab.</p> <p>PQM had a meeting with HCM IDQC management in Jan to obtain updates on their preparation of WHO PQ</p>	<p>PQM experts helped review the HCMC IDQC quality manual.</p> <p>A quality management team of HCM IDQC is established and a study tour to gain some insight and experience into other labs that have WHO PQ was undertaken.</p>	Due to security issues in Thailand and some demonstrations in Vietnam, the assessment trip to Vietnam in combination with regional assessment trips was postponed to Aug or Sep	Delayed to FY15 Q1

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		documents, provide advice on WHO PQ process and procedures, and schedule the QMS assessment (May 2014) and submission to WHO PQ (Sep 2014).			
Provide TA towards ISO/WHO PQ; assess and report progress		PQM helped review the NIDQC micro lab design	Upgrading of the NIDQC microbiological lab is ongoing	Ongoing	Upgrade of HCMC IDQC microbiological lab is complete with the national budget. Upgrade of the NIDQC microbiological lab is ongoing. PQM is reviewing the design of the current microbiological lab in compliance with WHO PQ requirements.
Provide TA on pharmacovigilance system within the framework of the Global Fund Round 10 project of the National DI&ADR Center at HUP					
Review all related documents, previous assessments, & reports (Continuing activities from FY13)		Pending for FY15	PQM met with the national PV center to discuss potential collaboration for FY15		For FY15, it is proposed that PQM provide technical assistance to develop a questionnaire on relevant quality measures in treatment failure and adverse effects reporting.
Train staff and develop operational manual for national and south DI&ADR Centers – Provide training in project mgmt to staff – Assist staff to adapt		Pending for FY15			Same as above

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Ops Manual for a PV center					
Maintain country consultant to improve project coordination, implementation, and effectiveness					
Support consultant's salary and misc. expenses for FY13		Country consultant participated in USAID/PEPFAR meetings and reported to PQM HQ and USAID/Vietnam in a timely manner	Country consultant participated in USAID/PEPFAR meetings and reported to PQM HQ and USAID/Vietnam in a timely manner	Country consultant participated in USAID/PEPFAR meetings and reported to PQM HQ and USAID/Vietnam in a timely manner	Country consultant participated in USAID/PEPFAR meetings and reported to PQM HQ and USAID/Vietnam in a timely manner
Provide laptop, office furniture and equipment			A laptop was procured in compliance with USAID and USP financial policy	Completed	Completed
Provide stationery, comms & admin costs		Done in compliance with the approved WP	Done in compliance with the approved WP	Done in compliance with the approved WP	Completed in compliance with the approved WP
Build and strengthen the capacity of the pharmaceutical management practices of the national ARV system at the peripheral/provincial levels, working towards a sustainable system					
Technical assistance for ARV's quality assurance through post-marketing surveillance in both public and private sectors					
A NIDQC analyst is trained in USP		PQM discussed with NIDQC and scheduled the training for May 2014 at Rockville	Logistics for NIDQC analyst's training are being finalized at USP HQ	A NIDQC qualified analyst attended technical training at USP HQ for 3 weeks in May	
Support NIDQC to hold the national technical training on ARV testing methods				The training workshop has been designed as a "training of trainers" and is scheduled for Aug. It is anticipated that 3 analysts from national and provincial QC labs will attend in addition to 10 analysts from the NIDQC.	The technical workshop was held in Aug with 13 trainees. To aid in cross-country efforts, three trainees were from Indonesia
Support VAAC, DAV to develop the post-marketing surveillance plan/QA & QC guideline for ARV quality		In discussions	In discussions	In discussions	In discussions

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Technical assistance to strengthen the capacity of Pharmaceutical Management Practices at the Peripheral Level for the ARV distribution system					
Contribute to the finalization of technical tools & documents		New workplan was prepared PQM attended a pre-testing workshop of technical tools and documents at HCMC PAC and provided comments for finalizing these tools	Workplan was approved by USAID mission PQM attended a technical meeting led by VAAC; joined with SCMC and CHAI to review and finalize the technical tools	Workplan was approved by USAID headquarters at the end of May	Completed
Present at HCMC and two regional training workshops and advise				PQM attended a regional training workshop in May at HCMC for Southern provinces	Completed
Provide TA to 12 provinces to install and use technical tools and documents				In progress	Planned for FY15
Provide administrative and program operation support					
Recruit two technical staff, one admin staff, and one part-time accountant/consultant				In Q4, job ads will be posted on NGO Resource Center and Vietnamworks websites; deliverables for the new staff are being prepared	Two technical consultants and one admin support staff have been identified. Contracts are being prepared at USP HQ.
Support salary for additional job allowance to COP-Consultant and fringe benefits				Scope of work for COP is being revised	Scope of work for PQM consultant/Management is being reviewed.
Support office rental and other office maintenance expenses				PQM is seeking office space for the in-country team; several options are being considered	Office options have been proposed and the USP legal department is reviewing them.
Procure office equipment and support other mgmt costs				Planned for Q4	Planned for FY15

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Review recruitment process of country office				Planned for Q4	Completed
Europe and Eurasia					
Kazakhstan J. Derry & K. Burimski					
Conduct baseline GMP assessments of Pavlodar Pharmaceutical Factory, provide technical assistance to the Factory towards reaching WHO Prequalification					
Conduct baseline GMP assessments of Pavlodar Pharmaceutical Factory		General assessment was conducted, trip report and confidential assessment report provided; thorough GMP assessment to be conducted once new facility is complete			
Provide technical assistance to the factory towards reaching WHO Prequalification			PQM team provided Guidance on GMP Principles to Pavlodar Pharmaceutical Factory, reviewed quality documents of the factory (SOPs), and provided their recommendations on improvements	PQM team followed-up on the results of the general GMP assessment and provided additional recommendations on CAPAs and SOPs	PQM staff visited Pavlodar and discussed implementation of CAPAs from PQM visit in Oct 2013. PQM visited the construction site of the new facility to assess the progress made since Oct 2013. Construction is planned to be completed by the end of 2015
Conduct one onsite general GMP training for specialists of Pavlodar Pharmaceutical Factory					
Conduct one general GMP training for the factory's GMP specialists			Tentative time for training determined – August 2014	Preparations for the training initiated, training agenda drafted and discussed with the Pavlodar Pharmaceutical Factory	GMP training for pharmaceutical professionals from second-line anti-tuberculosis medicine manufacturers located in Kazakhstan conducted
Support two GMP consultants for onsite work at Pavlodar Pharmaceutical Factory					
Support one consultant on QMS to provide 3-			Scope of work identified and agreed with	Teleconferences with a number of potential	A QMS consultant approved by Pavlodar;

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
mo. onsite/3-mo. remote TA			Pavlodar Pharmaceutical Factory; potential consultants identified and their CVs collected	consultants held; preferable candidates identified	tentative work plan developed by the consultant; contract preparation has begun
– Set up documentation system					
– Train staff on its use and on SOPs					
Support one consultant on Validation to provide 1.5-mo. onsite/1.5-mo. remote TA			Scope of work identified and agreed with Pavlodar Pharmaceutical Factory; potential consultants identified and their CVs collected	Teleconferences with a number of potential consultants held; preferable candidates identified	A validation consultant approved by Pavlodar; tentative work plan developed by the consultant; contract preparation has begun
– Assist w/construction and start-up of new mfg facility to ensure compliance					
Translate technical documents for Romat Pharmaceutical into English					
Provide translation services to prepare GMP certification and WHO PQ documents into English				No progress	No progress
Identify, assess, and support additional manufacturers for WHO Prequalification					
Conduct baseline assessments of select anti-TB medicines mfrs				Contacts with three additional manufacturers of anti-TB medicines established; the questionnaire intended to facilitate the process of evaluating pharmaceutical manufacturers interested in receiving technical assistance was sent to	Nobel Almaty Pharmaceutical Factory filled out the PQM questionnaire. PQM staff met with a representative of Nobel and discussed WHO PQ

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				them	
Provide TA to promising companies to improve their GMP compliance					Potential TA to Nobel was discussed. A PQM audit of the Nobel facility is scheduled for Oct 2014
Translate WHO Prequalification documents into Russian for manufacturers of anti-TB medicines					
Determine whether or not these documents already exist			The set of documents has been additionally reviewed; confirmation from WHO obtained that the versions of the documents are up-to-date and there is no translation into Russian; 2 documents will be taken for translation		
Perform translation, scientific editing, proofing, and formatting				Translator identified	Contract preparations are in progress
Expand the pool of viable manufacturers of anti-TB medicines by raising awareness of WHO PQ/PQM technical assistance program					
Conduct two-day workshop for mfrs in Central Asian Region on WHO PQ and PQM TA available				Dates of the workshop determined – October 2014 Preliminary agenda for the workshop was developed; potential speakers identified and contacted	The workshop was cancelled; however, PQM will participate in the Central-Asian Trade Forum IV in Almaty in Oct and deliver presentations on GMP requirements and the benefits of WHO PQ
Uzbekistan	J. Derry and K. Burimski				
Identify gaps in the country's medicines quality assurance system and propose interventions to address them					
Conduct a field gap analysis to identify status of QA/QC systems for anti-TB medicines to help define priority needs				PQM assessment visit scheduled for Aug Visit agenda developed, anticipated contacts discussed and agreed	PQM travelled to Uzbekistan but was not allowed to visit and assess the capacities of the key institutions

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				upon with Uzbek partners	
Meet with Uzbek national MRA, Ministry of Health, and relevant partners to discuss findings				Meetings with the MRA, MOH, and other relevant partners scheduled for the August visit	PQM met with representatives of all key government institutions at the MOH. For further TA, PQM needs to conduct a comprehensive situation analysis of targeted areas. Trip report provided.
Latin America and the Caribbean					
Amazon Malaria Initiative V. Pribluda					
Strengthen quality assurance and quality control systems					
Build capacity to perform Level 2 testing (Brazil)					
Reinstate rapid testing in endemic areas of Brazil			Discussions held with the NMCP and PAHO/Brazil to plan a meeting with ANVISA	In discussions with the NMCP, it was agreed that PQM would send a proposal to complement the QC support provided to the NMCP by PAHO and the School of Pharmacy of the Federal University of Minas Gerais. Subsequently PQM sent the proposal to NMCP, which was forwarded to ANVISA (Brazil MRA)	The NMCP accepted the proposal and the implementation plan that PQM sent. The plan was included in AMI's FY15 work plan presented at the Steering Committee Meeting in Sep 2014.
- Develop policy for ANVISA					
- Provide logistical support for training on basic tests					
Build capacity to perform Level 3 testing according to registration methodologies					
Support USP internship for Suriname OMCL staff member on QMS		2 staff of the BGVS lab in Suriname completed a 3 week internship at			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		USP on pharmaceutical analysis of antimalarial medicines			
Conduct training on testing of AMLs for the Suriname lab					
Conduct proficiency testing on Coartem [®] to evaluate regional OMCL capabilities				Process to implement inter-laboratory proficiency testing of Coartem initiated Samples of Coartem purchased and support documentation sent to the labs; samples will be sent at the beginning of Q4	Samples and reference standards were sent to Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname. Ecuador and Peru completed analysis, and results will be reviewed FY15 Q1
Implement three-level approach for sustainable medicines quality monitoring activities throughout the supply chain					
Support MRAs and NMCPs of Colombia, Guatemala, Peru and Suriname to expand implementation of 3LA to decentralized areas			Initiated coordination between MRA and NMCP to include antimalarials in MQM activities Provided guidelines to MRA, OMCL, and Loreto's Regional Medicines Office for expansion of methodologies for implementation of the Three-Level Approach		Coordinated the shipment of reference standards to the Guatemala lab for the analysis of antimalarials
Implement 3-level approach in Ecuador				The MRA and lab in Ecuador underwent changes recently. No feedback was provided by stakeholders to PQM requests to fulfill proposed plans	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Finalize MOU and documents to implement 3-level approach in Guyana				Request to finalize MOU was sent to the country but there was no follow-up by stakeholders	
Identify and establish mechanisms to ensure sustainable south-south collaborations among OMCLs and MRAs in AMI countries					
Conduct a regional workshop to discuss sustainable mechanism to foster/support south-south collaborations			Initiated discussions with international partners to develop terms of reference for attendants	Terms of reference were finalized Academic institutions to be invited were identified Stakeholders agreed that the workshop will be conducted in FY15 Q1	Workshop will be delivered in Nov 2015 in Lima, Peru. Invitations were sent to MRAs and OMCLs from 18 countries and 8 academic institutions from 5 countries, all in LAC. Participants include non-AMI LAC countries who will be supported independently by USP.
Combating substandard and counterfeit medicines					
Develop virtual library of images of antimalarials in use in AMI countries					
Coordinate with local authorities to study MQ in Peru decentralized areas w/new 3-LA regs			The scope of the tool has been expanded beyond images to assess most relevant information included in the visual and physical inspection of medicines. Pilot assessment of the tool will be done in Colombia and/or Peru, because both countries are the most advanced in the institutionalization of the Three-level Approach		
- Identify entity to develop library			Six potential consultants identified and a request for proposals is being developed; will be sent	RFP finalized and sent to potential consultants Based on responses two	Contractor selected and final scope of work finalized. Contract will be signed and work initiated

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			by early Q3	potential consultants have been identified and are currently being evaluated Final contractor selection and initiation of work will occur in Q4	during FY15 Q1. Work will be financed AMI and other PQM funding streams. Pilot usage will be implemented in 5 countries including 2-3 from AMI
- Assess methodology					
- Access medicines info in countries					
- Create library in a format for distribution					
- Disseminate information					
Provide technical leadership and global advocacy					
Disseminate results of quality study performed in three departments in Colombia					
Develop final report w/ country stakeholders; disseminate internally		The report was prepared by PQM and circulated internally			
Develop draft for wider dissemination by publishing results in peer-reviewed media					
Disseminate information about PQM activities					
Develop draft and submit to peer-reviewed journals			Papers accepted and published: - Were medicine quality and pharmaceutical management contributing factors in diminishing artemisinin efficacy in Guyana and Suriname? Malaria Journal 2014, 13:77 - The Three-level Approach: A framework		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			for ensuring medicines quality in limited resource countries Pharmaceut Reg Affairs 2014, 3:1		
Attend Meetings					
Attend semi-annual Steering Committee and annual RAVREDA technical meetings			Attended and presented at meetings in Nicaragua in March		Attended and presented at the AMI Steering Committee Meeting in Washington DC. PQM AMI FY15 work plan was presented and discussed
Guatemala V. Pribluda					
Strengthen quality assurance and quality control systems					
Build regulatory capacity					
Upgrade DRCPFA's registration software to allow internet access for registration (WebSIAMED) *This activity is conducted with carryover funding from the FY13 Work Plan		Upgrade of online registration renewals completed. Pilot assessment of online renewal with selected manufacturers was successful	16 training sessions offered to prospective users. There were 110 applications, of which 65 were approved in 48hrs; the rest failed adjustments. 70 professionals registered to use the system. Online regular registration will start in May 2014 and the system will be fully operational by the end of Q3	Online renewal of registrations is fully operational. By May, more than 200 applications have been processed Starting June 2014, all applications are processed exclusively online The launch for all registrations (new and renewal) planned for Q4	Due to changes in health authorities, the final launch was postponed. New authorities confirmed that launch will occur during FY15 Q1
Train MRA medicines registration staff on dossier evaluation			Training coordinated with MRA to be delivered in June	This training was rescheduled for July because the training on equipment and water/air system validation was delivered in June (see below)	Training for MRA personnel was delivered in July.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Build OMCL capacity to perform QC testing					
Ensure OMCL operations are in compliance w/int'l standards					
– Review QMS documentation			Documentation requested from OMCL and review initiated	All documentation sent was reviewed	
– Assess UM-LNS to follow-up previous CAPAs			Assessment visit planned for May	Assessment visit completed in May; a full report was sent to the lab and a trip report sent to appropriate stakeholders	
– Establish road map to expand scope and attain ISO 17025 accreditation				Lab management committed to expansion of accreditation and a tentative road map was sent to lab management Pending the availability of funds, and if all observations are addressed, an audit for expansion of the accreditation is planned for FY15 Q1	The lab was re-accredited by the Guatemalan Accreditation Organization after voluntary suspension in 2013. The lab requires supplies and equipment for the expansion of its accreditation. Currently exploring new possible mechanisms for the donations of those because it cannot be done through PAHO anymore
Strengthen proficiency in quality control testing					
Conduct trainings on GLP, Karl Fischer, Dissolution, UV-Vis					Due to the cessation of funding by the Mission for FY15, these activities have been temporarily suspended until remaining funds are prioritized
Implement three-level approach for sustainable medicines quality monitoring					
Support MQM at			Protocol for MQM in	Trainings and sampling in	MRA regulations that

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<p>selected 'Area(s) de Salud' utilizing the three-level approach (Huehuetenango Health Area)</p> <p>*This activity is conducted with carryover funding from the FY13 Work Plan</p>			<p>Huehuetenango completed</p> <p>MQM activities coordinated with MRA, Health Area Office, and the OMCL will be performed in April</p>	<p>health centers performed</p> <p>Samples that cannot be screened with the Minilab were sent to the lab for analysis; USP Reference Standards required for analysis were donated to the lab</p> <p>Sampling at the hospital and storage facilities still needs to be conducted</p> <p>MQM report is being prepared</p> <p>As a follow up to this activity, and in discussion with the MRA, the regulations for MQM are in the process of being modified to include the Three-level Approach; the modified regulations are being finalized by the MRA to be sent for approval</p>	<p>include the Three-level Approach have been developed and reviewed by PQM and the MRA. The final version is ready for submission to the MoH for approval. Submission was planned during this quarter but had to be postponed because of the changes in health authorities. Authorization expected during FY15 Q1.</p>
<p>Expand MQM activities to additional areas.</p>					<p>Due to cessation of funding by the Mission for FY15, these activities have been temporarily suspended until remaining funds are prioritized.</p>
<p>– Equip sites with Minilab[®] and supplies</p>					

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
– Provide support to MRA, DAS, OMCL for logistics/supplies					
Increase the supply of quality assured medicines					
Strengthen DRCPFA capabilities to ensure manufacturers comply with current Good Manufacturing Practices					
Train DRCPFA staff on equipment, and water & air system validation			Training coordinated with MRA to be delivered in July	Training delivered in June 2014 instead of July 2014 (see above)	
Provide oversight, monitor and evaluate PQM programs					
Meet w/country stakeholder to plan activities, follow up on implementation, report PQM achievements			PQM had several virtual meetings with country stakeholders (MRA, OMCL, and USAID) to coordinate and advance the implementation of activities; in-country visit is planned for May	PQM met with MOH, OMCL, and the MRA during the May visit	