

## Progress on FY08 Workplan Activities

Activity	Staff Lead	Progress				Indicators	Impact	Remarks
		Q1	Q2	Q3	Q4			
<b>Common Agenda</b>								
<b>Objective: Support global health initiatives by providing up-to-date information about current issues in drug quality and appropriate use.</b>								
Activity 1. Maintain and update the DQI website.	M Foster	Added 24 new articles, 21 photos, 40 DI updates; updated 3 existing web pages and 3 AI reports; added or updated 3 resource materials	Added 7 articles, 6 photos, updated 2 existing web pages and AI report, added interactive request form for TB TA, added HE Yim Yann video, expanded PSAs from 1 to 4 versions	Added 9 articles, 11 photos, updated 1 web page and 1 AI report	Added 6 articles and 7 photos; updated 2 web pages, 1 AI report, and 3 resource materials.	# new articles added; # new or updated resources added; # pages updated		
Activity 2. Update and promote the <i>Matrix of Drug Quality Reports Affecting USAID-assisted Countries</i>	M McGinnis	Updated Matrix with 23 new reports; 4,403 website hits	Updated Matrix with 25 new reports; 4,350 website hits	Updated Matrix with 30 new reports; 4,685 website hits	Updated Matrix with 27 new reports; 5,842 website hits	# of reports added; # of website hits	increased awareness of up-to-date substandard/counterfeit drug situation	Beginning Feb 2009, Matrix is updated monthly
<b>Objective: Stimulate the interest of stakeholders in drug quality work.</b>								
Activity 1. Attend and participate in international conferences on drug quality and present at at least one conference.	P Lukulay	GDF conference in Rio de Janeiro planned in March. Will present GMP templates prepared for manufacturers.	Attended and presented DQI technical assistance to second-line anti-TB drug manufacturers in Rio de Janeiro, Brazil. Conference was attended by GDF, UNITAID, Clinton Foundation, and anti-TB drug manufacturers	Exhibited at GHC conference; prepared two flyers on DQI program/activities and one flyer on DQI TB dossier prep assistance	Delivered plenary lecture at the 10th Commonwealth Pharmacists Association in Ghana in August. Title of presentation: "Threats of counterfeit and substandard medicines to global public health"	Conferences identified for FY 09; presentations made		
<b>Objective: Build institutional competencies to support the appropriate management and use of pharmaceuticals</b>								
Activity 1. Produce e-Learning course on drug quality.	A Barojas	Course content has undergone minor internal & USAID reviews and revisions.	Course content has undergone further internal & USAID revisions and is ready to be distributed to entire DQI department for internal revision.	Course was reviewed internally by all DQI staff and changes were incorporated. Per discussions with USAID, course was then split into two courses, one introductory and one technical in-depth course. The two courses were submitted to USAID CTO for review. USAID performed a preliminary review and requested changes, development of quiz questions, and an outline for each course. USAID's comments were incorporated into the courses and the outline and quiz questions for the first course were re-submitted to USAID for review.	Waiting for response from USAID per Q3 actions.	Obtain DQI staff approval; Obtain CTO approval; Obtain USAID E-Learning Center approval	USAID staff and other stakeholders will have an introductory course freely available on the internet to on issues related to drug quality and how to assure the quality of medicines, focusing on developing country context.	Material has been distributed for DQI staff review. Staff comments will be integrated and course sent for CTO review in Apr/May 09. Following CTO approval, the material will be transferred to the online server and reviewed by the USAID E-Learning Center Manager before going live. This will occur Q3-Q4.
Activity 2. Supplement USAID Country Mission funds for continuation of QAMSA.		Samples from Madagascar Senegal, and Uganda have been received at USP/Rockville. Confirmatory testing of more than 200 products from these samples are in progress. Testing is completed for approximately one-third of these products.	Preliminary results of compendial testing for samples from Uganda, Madagascar and Senegal have been sent to USAID. Final result and report due in next quarter.		QAMSA report has been completed and is being sent to countries for their information	Samples shipped to USP/Rockville lab; Samples tested and data reviewed; findings documented; report disseminated		
Activity 3. Conduct an assessment of DRA and NQCL in Zambia.			This activity was not approved by USAID/Zambia PMI team			Assessment plan developed and approved; on-site assessment conducted; report disseminated to stakeholders; draft workplan submitted to CTO		Statement of Work (SoW) to be developed and sent to USAID Zambia mission in Q2.
<b>P.E. 3.1.2: Tuberculosis (TB)</b>								
<b>Objective: Strengthen implementation of DOTS (3.1.2.1) expansion and enhancement through standards development and guidelines.</b>								
	P. Lukulay							In Q3, the DQI director met with the WHO Prequalification team in Geneva. The WHO team committed to working closely with DQI to reach common goals

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<b>Objective: Reduce the spread of MDR- and XDR-TB through better access to second-line treatment. (3.1.2.4)</b>							
<b>Activity 1.</b> Provide technical assistance to manufacturers of second-line TB medicines seeking to obtain WHO prequalification.	Kiltch (India) dossier accepted by WHO for detailed review. Planned face to face meeting to review WHO comments	A second visit to Kiltch was conducted to assist them in responding to WHO questions on the dossier. Dossier with all responses will be resubmitted in May. Has received request from Svizera (PAS, Capreomycin), Russian manufacturer for assistance toward prequalification. Workshop planned in next quarter for Brazilian manufacturers of SLD.	DQI worked with Kiltch to address comments made by WHO on the dossier and API information is pending; awaiting 2 dossiers for review from Svizera (India) prior to submission to WHO; SIA (Russia) dossier in preparation stages and is being translated into English. DQI is planning a trip to SIA in August 2009; UNILAB (Philippines) has requested assistance for dossier prep and a teleconference is scheduled for July 2009; Several companies in Brazil will attend a workshop planned for September (in collaboration with MSH/SPS) to familiarize them with PreQ. Invitation letters and questionnaire have been translated into Portuguese.	Reviewed 4FDC dossier (Etambutol+ Isoniazid +Rifampicin+Pyrazinamide) oral powder formulation dossier from Svizera and made 3 recommendations to improve Module 3	# dossier submitted to WHO. # of companies prequalified		
1.1 Identify and confirm from GDF, list of priority products and potential manufacturers for prequalification. Develop guidelines (Check list) for 1.2 Visit and Evaluate 4-6 manufacturers/products for support toward prequalification 1.3 Conduct GMP audits, develop inspection reports, and prepare manufacturer's for WHO inspection.		Template developed for dossiers submitted for WHO prequalification and shared with manufacturers.		Identified Unilab in the Philippines as a candidate for dossier TA  Visited Syntez Pharmaceutical in Russia for a baseline GMP assessment  Nondisclosure agreement signed with Unilab in Philippines and PQM GMP staff will visit in December 2009	Initial GDF list received; priority products matched to mfrs; questionnaire developed; 6 best dossiers developed and screened; dossiers submitted to WHO  # GMP audits performed on mfrs (4); # inspection reports (4)		GDF posted link to DQI website and TA for dossier preparation.
<b>Activity 2.</b> Conduct activities related to GDF programs.	DQI director went to Geneva to develop a priority list of second line TB medicines and companies to receive technical assistance. Eight new manufacturers have been contacted and informed about DQI TA. Awaiting responses.		Attended GDF meeting in Rio, Brazil and presented DQI work to various stakeholders including UNITAID, various manufacturers, WHO, Clinton Foundation	Arranged meeting with WHO Prequalification team on Nov 30, 2009			
<b>Activity 3.</b> Develop pharmacopeial monographs for second-line TB drugs.	Contacts have been made with two companies in India.			Methods for Prothionamide obtained and in development  Minilab methods developed for three second-line TB medicines	Two medicines selected; two monographs developed		
<b>3.1</b> Identify 2 second-line TB medicines without public standard.							
<b>3.2</b> Develop documentary and reference standards and publish in SALMOUS.		Svizera indicated that they will send methods for Prothionamide					
<b>P.E. 3.1.3: Malaria</b>							
<b>M. Hajjou</b>							
<b>Objective: Promote cooperation on drug quality issues through a Drug Quality Monitoring network. (3.1.3.0)</b>							

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Activity 1.	Develop a network of drug quality monitoring countries in Africa (Senegal, Uganda, Ghana, Ethiopia and Madagascar).	Contacts with countries are being made and venue for first workshop has been determined.	Participating countries contacted; Workshop planned for July 2009		Workshop conducted in September in Accra, Ghana; Participating countries were: Ethiopia, Ghana, Mali, Senegal, and Uganda; Objectives and goals of the network defined; Letters sent to heads of DRAs or MoHs to seek official approval for membership; a one-year work plan was drafted	Network established and functional; Member-identification wksp conducted; guidance document produced and disseminated to members; data-sharing documented	
<b>Objective: (3.1.3.6) Support multi-country study of the quality of ACTs and SPs in PMI-supported countries</b>							
Activity 2.	Support Senegal and Uganda in conducting confirmatory testing.	Training has been completed and Minilab testing by the USP-supported countries has been completed. Confirmatory testing of more than 200 products from these countries is in progress at USP/Rockville lab.	Confirmatory testing will be completed in May	Confirmatory testing completed for the samples from Madagascar, Senegal and Uganda. Draft report is under review.	Final report drafted and reviewed by USAID; comments will be incorporated and report finalized in FY10 Q1	Training conducted; confirmatory testing done in all USP-supported countries; report generated and disseminated	
<b>Objective: (3.1.3.1) Develop pharmacopeial monograph for an ACT drug.</b>							
Activity 3.	Develop pharmacopeial monographs for key antimalarial medicines.	Manufacturers have been identified for priority antimalarials and contacts are being made in conjunction with USP Standards Acquisition Department to solicit for analytical data to develop these monographs	Sanofi-Aventis/Morocco has been contacted; waiting for analytical data	Awaiting analytical data	Awaiting analytical data	Mfr identified and contacted; comparative testing completed and reported; quality specs documented; monograph drafted for public comment; monograph published in SALMOUS	
<b>P.E. 3.1.4: Avian Influenza</b>		<b>S Phanouong</b>					
<b>Objective: (3.1.4.1) Plan and Prepared for Outbreak Response</b>							
Activity 1.	Test oseltamivir samples as needed.	Compendial methods under final review	No samples were tested	No samples were tested		# samples tested	Ensure and maintain the quality of oseltamivir products from manufacture and acquisition to use
Activity 2.	Produce quality specifications for oseltamivir.	2 content sections added (out of 7 total): 1. "quality characteristics of API" and 2. "quality characteristics of finished dosage forms"	Document drafted and being edited. The edited document will be sent out for review in Q3.	Edited document was sent for internal and external review; comments received	Incorporating comments	One document developed in collaboration with partners	Increased access to technical guideline resource for ensuring the quality of oseltamivir products Technical guidelines directed at gov and non-govt agencies for procurement, distribution, etc for ensuring quality of oseltamivir products
<b>P.E. 3.1.6: Maternal Health and Child Survival</b>		<b>E Toledo</b>					
<b>Objective: (3.1.6.6) Prevent and treat childhood diarrheal illness</b>							
Activity 1.	Conduct quality control/GMP assessment of zinc manufacturers for global and local supply	Performed GMP audit on Shelys and Zenufa; reports disseminated	Performed GMP audit on DJPL,NPL, CTL and Lomus in Nepal; reports disseminated			GMP assessments successfully conducted, reports presented to stakeholders	Zinc dossier received from DJPL for review and compilation. Will be submitted as part of WHO Zinc EoI
1.1	Conduct GMP visits at Shelys Pharmaceutical in Tanzania for evaluation of correctives action implementation		Assisted Shelys to enable them to submit dossier in June for WHO prequalification	Performed dossier review at Shelys. Evaluated corrective actions and zinc formulations at Zenufa. Report disseminated.	Visited Shelys and reviewed dossier prior to submission in July. Shelys zinc dossier was accepted by WHO. UNICEF purchased ORS from Shelys and will inspect the facility in the first half of 2010.	GMP assistance successfully conducted, report presented to stakeholders	
1.2	Conduct a baseline GMP assessment at Zenufa Laboratories in Tanzania		Completed		Tanzania FDA granted Zenufa zinc syrup registration	GMP assistance successfully conducted, report presented to stakeholders	
1.3	Develop corrective action plan and provide technical assistances for Tanzania manufacturers on dossier and general GMP implementation					Corrective action plan drafted and sent to manufacturer for implementation	

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1.4 Conduct GMP visits at DJPL, NPL and CTL Pharmaceuticals in Nepal for evaluation of correctives action implementation					GMP assessments successfully conducted on 3 mfrs; reports presented to stakeholders	
1.5 Provide technical assistances for Nepal manufacturers on dossier compilation and general GMP implementation			Assisted DJPL to enable them to submit the dossier in August for WHO prequalification	Continue support to DJPL on zinc dossier	Corrective action plans (3) drafted and sent to manufacturers for implementation	
1.6 Conduct baseline GMP assessment at Lomus Pharmaceutical Nepal to evaluate facilities ( for zinc manufacturing activities)				Continue support on zinc dossier		
Activity 2. Develop two additional pharmacopoeia monographs on zinc (acetate and gluconate formulations).	Zinc Gluconate monograph drafted and put in PF. Will be published late in 2009. Zinc Acetate monograph contacts being sought.	Zinc Gluconate oral solution mograph acquired from Indian Manufacturer (Shalacks Pharmaceutical ); forwarded for review and publication			Each monograph received and validated	Reduce cost of zinc by increasing local capacity for production and improving procurement of good quality zinc products by UNICEF and other procurement orgs
2.1 Monograph for zinc acetate procured and published.						
2.2 Monograph for zinc gluconate procured and published.						
Activity 3. Conduct drug quality testing of zinc samples submitted by UNICEF, USAID Missions, and partners.			Samples from zinc manufacturers in Indonesia, India, and Nepal were received for testing		Number of samples tested and results (goal=40); report presented to appropriate stakeholders	Zinc gluconate monograph will be published in USP PF35(3) Nutriset and Square signed a contract with UNICEF for zinc tender requesting zinc sulfate samples from Indonesia; samples on the way;
3.1 Perform qualitative and quantitative procedures to determine identity, strength, purity, and quality of products.						
3.2 Share results with UNICEF, USAID Missions, and partners.						
<b>Objective: Improve newborn health outcomes (3.1.6.2)</b>						
Activity 1. Conduct Quality Control/GMP assessment of a chlorhexidine manufacturer (Lomus Pharmaceutical Nepal) for global and local supply.	GMP assessment conducted in January and corrective actions being drafted	GMP report disseminated		Continue support on chlorhexidine manufacturing activities	GMP assessments successfully conducted. Reports presented to stakeholders	
1.1 Conduct GMP assessments at selected manufacturers of chlorhexidine.						
<b>Objective: Improving coverage and supplementation of vitamin A for children under 5 (3.1.6.5)</b>						
Activity 1. Develop pharmacopoeial monographs for Vitamin A Gelcaps as requested by USAID.	Monograph drafted and put in PF for review				Monograph received and validated	