

## **Training on Pharmaceutical Process Validation**

**Alabang, Muntinlupa City, Philippines**

November 13-16, 2012

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### ***Trip Report***

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### **Promoting the Quality of Medicines**

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**PROMOTING THE QUALITY OF MEDICINES**

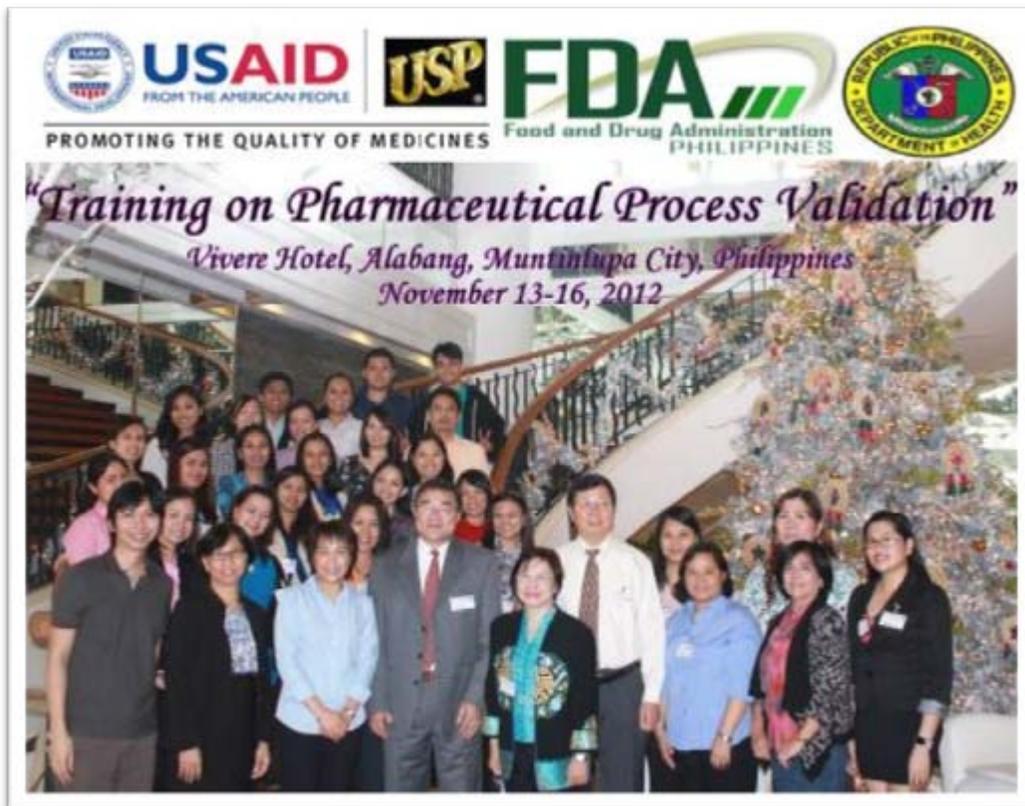
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## Executive Summary

At the request of the Philippines Food and Drug Administration (FDA) to promote the use of internationally accepted quality standards, specifications, and dossier review practices, a PQM team conducted a successful process validation workshop from an industrial perspective. This workshop introduced stringent regulatory agency requirements as well as best pharmaceutical industrial practices.

The PQM team also participated in the FDA's "National Consciousness Week against Counterfeit Medicines," where Dr. Souly Phanouvong was a guest speaker. At the venue, a photo exhibit of "Pharmacide Arts" was displayed for public viewing.

While in-country, the PQM team also attended meetings with the Philippines FDA for programmatic updates; potential second-line anti-tuberculosis medicines manufacturers to follow-up with those who have an interest in the World Health Organization (WHO) Prequalification (PQ) program; WHO's Office for the Western Pacific Region (WPRO) to explore collaboration opportunities; and several universities to explore the concept of a Bioavailability/Bioequivalence (BA/BE) Center in the Philippines.



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### **About PQM**

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

## ACKNOWLEDGEMENTS

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- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington; Dr. Patrick Lukulay and Dr. Kennedy Chibwe at USP Headquarters; Ms. Ann Hirschey and Dr. Yolanda E. Oliveros at USAID/Philippines; and Dr. Kenneth Hartigan-Go at FDA Philippines, for their support and advice
- PQM administrative and editorial staff for their support with logistical arrangements and for editing the trip report
- Ms. Nazarita T. Tacandong for giving the welcome and opening remarks and for extending her time and assistance at the training.
- Dr. Bill Wei for giving the well-prepared lectures and insights on process validation
- Ms. Maria Lourdes C. Santiago at the Philippines FDA for her guidance, support, and commitment

## ACRONYMS

ATB	Anti-Tuberculosis Medicines
AUSAID	Australian Government Overseas Aid Program
BA/BE	Bioavailability/ Bioequivalence
CHD	Center for Health Development
DOH	Department of Health
DQI	Drug Quality and Information Program
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FDRO	Food and Drug Regulation Officer
GPHF	Global Pharma Health Fund
LGU	Local Government Unit
MQM	Medicine Quality Monitoring
NCDPC	National Center for Disease Control and Prevention
NTP	National Tuberculosis Program
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization
WPRO	WHO Western Pacific Region

## Background

Since 2007, with financial support from the United States Agency for International Development (USAID), the United States Pharmacopeia (USP) has been actively providing technical assistance to the Philippines Food and Drug Administration (FDA), the Department of Health (DOH), and the National Tuberculosis Program (NTP) in an effort to strengthen medicines quality assurance and quality control (QA/QC) systems. Assistance has focused on establishing a post-marketing surveillance program—known as the medicines quality monitoring (MQM) program—to monitor the quality of anti-tuberculosis (TB) medicines available on the market and enhancing the FDA’s regulatory capacity in evaluation and registration of pharmaceutical products.

## Purpose of Trip

- The primary objective of this trip was to provide training for Philippines FDA officials on process validation from an industry perspective
- Secondary objectives of the trip including attending and presenting at the Philippines FDA “National Consciousness Week against Counterfeit Medicines”; meeting with the Philippines FDA for programmatic updates; meeting potential second-line anti-tuberculosis medicines manufacturers to follow-up with those who have an interest in the World Health Organization (WHO) Prequalification (PQ) program; meeting with WHO’s Office for the Western Pacific Region (WPRO) to explore collaboration opportunities; and meeting with several universities to explore the concept of a Bioavailability/Bioequivalence (BA/BE) Center in the Philippines

## Source of Funding

These activities were funded by USAID/Philippines.

## Overview of Activities

The training activities are summarized in the following table:

Item	Description
Specific Objectives	Assist the participants to become familiar with stringent regulatory agency requirements on pharmaceutical process validation for active pharmaceutical ingredient (API) and for different dosage forms.
Venue/Location	Vivere Hotel, Filinvest Corporate City, Alabang, Muntinlupa City, Philippines
Organizers	PQM and the Philippines FDA
Sponsors	USAID/Philippines
Trainers and Facilitators	<ul style="list-style-type: none"><li>• Dr. Allan Hong, PQM</li><li>• Dr. Bill Wei, Pharmaceutical Industry Consultant</li><li>• Dr. Souly Phanouvong, PQM</li><li>• Maria Kathrina D. Olivarez, PQM</li></ul>
Trainees	26 participants; See Participant List in <i>Annex 1</i> for detailed information.
Agenda	See Agenda in <i>Annex 2</i> for detailed information

Opening Ceremony	<ul style="list-style-type: none"> <li>• Nazarita Tacandong, FDA</li> <li>• Maria Lourdes Santiago, FDA</li> <li>• Maria Kathrina Olivarez, PQM</li> </ul>
Modules	<ul style="list-style-type: none"> <li>• Validation Background</li> <li>• API Process Validation</li> <li>• Dosage Form Process Validation</li> <li>• FDA Case Studies/Dossiers</li> </ul>
Closing Ceremony	<ul style="list-style-type: none"> <li>• Allan Hong, PQM</li> <li>• Souly Phanouvong, PQM</li> <li>• Liza Pajarillo, FDA</li> <li>• Certificates of completion were given to the participants</li> <li>• Certificates of appreciation were given to the trainers and facilitators</li> </ul>
Training Evaluation	See participant evaluations of each module in <i>Annex 3</i>
Outcomes/ Conclusion	At the end of the training, participants were able to understand stringent regulatory agency requirements on Pharmaceutical Process Validation for API and for different dosage forms.
Next Steps	Philippines FDA officials will contact PQM if they have further questions on process validation practices.

### Training commentary

The process validation workshop for the Philippines FDA was designed to be interactive, and all of the presentation materials were based on industry examples to demonstrate how process validation is practiced by the innovator and generic pharmaceutical industry.

During the workshop, the group evaluated and commented on three Philippines FDA working dossiers, page by page, to demonstrate the necessary technical details. Following the workshop, a Q&A session was held to address current issues that the trainees are having during their dossier review process.



### **Additional Activities and Meetings**

The agenda and photos from the “National Consciousness Week against Counterfeit Medicines” can be found in *Annex 4*. In *Annex 5*, minutes of the following meetings can be found:

- Philippines FDA for programmatic updates
- Potential second- line anti-tuberculosis medicines manufacturers to follow-up with those who have an interest in the WHO PQ program
- WPRO to explore collaboration opportunities
- Several Philippines universities to explore the concept of a BA/BE Center in the Philippines

**PARTICIPANT LIST**

ALIM, CHERRY V.	Laboratory Services Division, FDA
ESCOBIA, JORGENE A.	Laboratory Services Division, FDA
LOPEZ, YVETTE MARTHA E.	Laboratory Services Division, FDA
TIO, MICHELLE S.	Laboratory Services Division, FDA
SISON, ELIZA G.	Product Services Division, FDA
CRUZ, CHERRY ROSE R.	Product Services Division, FDA
PAJARILLO, LIZA S.	Product Services Division, FDA
SALUD, RUBY R.	Product Services Division, FDA
MANALUNDONG, DJAMAL M.	Product Services Division, FDA
ORTALIZA, MARIDEL P.	Product Services Division, FDA
LEGASPI, ROMAR C.	Product Services Division, FDA
MOLINA, ALELI B.	Product Services Division, FDA
BINOS, RICHARD SIMON R.	Product Services Division, FDA
TIBI, ARLYN JOY G.	Product Services Division, FDA
BANDOMA, TRISTAN ARIES C.	Product Services Division, FDA
DUMLAO, ANGELI, MAE P.	Product Services Division, FDA
DE LUNA, FRANCES GLORIE D.	Regulatory Division I, FDA
COLLADO, JENNIFER JOANA G.	Regulatory Division I, FDA
FRANCISCO, MARY ANGELINE V.	Regulatory Division II, FDA
ORTILANO, RIORIZA A.	Regulatory Division II, FDA
CASALA, ANGELI B.	Regulatory Division II, FDA
OPENA, SHERALYN A.	Regulatory Division II, FDA
MENDOZA, CLARISSA A.	Region III, FDA
DE SAGUN, MA. LUISA L.	Region IV-A, FDA
NUESTRO, MELINDA A.	Region IV-A, FDA
CASTRO, GINA C.	Academe, University of Sto. Tomas

**OBSERVERS**

TACANDONG, NAZARITA T.	Director III, FDA
SANTIAGO, MARIA LOURDES C.	Chief, Laboratory Services Division, FDA
LABOY, VIRGINIA FRANCIA C.	Chief, Product Services Division, FDA
ASPREC, WENZEL C.	Product Services Division, FDA
ESCUETA, LILIBETH K.	Industry, Amherst Laboratories Inc.

**TRAINERS/ FACILITATORS**

HONG, ALLAN	Manager, GMP, PQM
WEI, BILL S.	Pharmaceutical Industry Consultant
PHANOUVONG, SOULY	Manager, Asia Programs, PQM
OLIVAREZ, MARIA KATHRINA D.	Country Consultant, PQM

**TRAINING AGENDA**

<b>Training on Pharmaceutical Process Validation</b>	
Vivere Hotel at 5102 Bridgeway Avenue, Filinvest Corporate City, Alabang Muntinlupa City, 1781, Philippines November 13-16, 2012	
<b>TUESDAY, NOV 13</b>	<b>ACTIVITIES</b>
8:30 – 9:00	Registration
9:00 – 9:15	Flag Ceremony/ Opening Prayer
9:15 – 9:30	Welcome Message: <b>Nazarita T. Tacandong, RPh, MPA</b> Director III, FDA
9:30 – 9:45	Opening Remarks: <b>Kenneth Y. Hartigan-Go, MD</b> Acting Director IV, FDA
9:45– 10:00	Introduction of the Trainers: <b>Maria Lourdes C. Santiago, MSc, M.M.</b> Chief, Laboratory Services Division, FDA
10:00-10:30	Group Photo/ Coffee Break
10:30 – 12:00	<ul style="list-style-type: none"> <li>• Opening meeting: <b>Dr. Allan Hong</b> GMP Manager Promoting the Quality of Medicines (PQM) Program <ul style="list-style-type: none"> <li>○ Review agenda, Training objectives and Expected outcomes</li> </ul> </li> </ul>
12:00 – 1:00	Lunch Break
1:00 – 5:30	<ul style="list-style-type: none"> <li>• Presentations: <ul style="list-style-type: none"> <li>○ Validation Master Plan</li> <li>○ Technology Development Report</li> <li>○ Active Pharmaceutical Ingredient Process Validation</li> </ul> </li> </ul>
Coffee Break (3:00 – 3:30)	
<b>WEDNESDAY, NOV 14</b>	<b>ACTIVITIES</b>
8:30 – 5:30	<ul style="list-style-type: none"> <li>• Presentations: <ul style="list-style-type: none"> <li>○ Oral Solid Dosage/ Capsule Process Validation</li> <li>○ Injectable Powder/ Solution Process Validation</li> <li>○ Oral Solution Process Validation</li> <li>○ Summary</li> </ul> </li> <li>• Discuss Philippine FDA Case Studies</li> </ul>
Coffee Break (10:00 – 10:30)	
Lunch Break (12:00 – 1:00)	
Coffee Break (3:00 – 3:30)	
<b>THURSDAY, NOV 15</b>	<b>ACTIVITIES</b>
8:30 – 5:30	<ul style="list-style-type: none"> <li>• Plant Visit: Amherst Laboratories, Inc. Unilab Pharma Campus, Brgy. Mamplasan Biñan, Laguna, Philippines</li> </ul>
<b>FRIDAY, NOV 16</b>	<b>ACTIVITIES</b>
8:30 – 5:30	<ul style="list-style-type: none"> <li>• Final Q&amp;A Session, Wrap-up and review of training activity</li> <li>• Complete evaluation sheets</li> <li>• Closing Ceremony <ul style="list-style-type: none"> <li>○ Message from: <b>Dr. Souly Phanouvong</b> Manager Asia Programs, USP PQM</li> <li>○ Presentation of Certificates of Completion and Appreciation</li> <li>○ Message from the participant: <b>Ms. Liza Pajarillo</b> (FDRO III, PSD)</li> </ul> </li> </ul>
Coffee Break (10:00 – 10:30)	
Lunch Break (12:00 – 1:00)	
Coffee Break (3:00 – 3:30)	

## PARTICIPANT EVALUATIONS

### Evaluation of Specific Aspects of the Training

	<b>Rating</b> (1 = Least satisfied; 5 = Completely satisfied)				
	1	2	3	4	5
<b>Overall Course Feedback</b>					
Content / topics covered				7	19
Format (e.g. lectures, labs demos, hands-on labs etc.)				10	16
Speakers knowledge of the subject matter				1	25
Speakers responsiveness to questions					26
Course length / Schedule / Time allotments / Pace			2	12	12
Usefulness of course material / hand outs			3	8	15
Usefulness / relevance of information to everyday practices				9	17
Course administrations / logistics			1	9	16
Extent to which course met your expectations overall				4	22
<b>About Specific Segments of the Course</b>					
Background Concepts				6	20
API Process Validation				8	18
Solid Dosage Validation				8	18
Injectable Validation				9	17
Oral Solution				9	17

### Other Comments/Suggestions:

#### 1. What did you like best about the course?

- The actual evaluation of documents, case studies and dossiers.
- The course provided background concepts and application of concepts through critique/ study of actual industry examples. The overall course was very effective in driving home understanding concepts.
- The curriculum was brief and concise however delivering the best knowledge for the participants.
- The training was realistic as we can easily apply it at work.
- The trainers are highly recommended for the course for which they have shown their outmost expertise at the training. They are very patient in answering all inquiries and questions from the participants.
- The plant visit/ tour were also very helpful and informative. Just to take a look at the equipment, facilities and environment was a good exercise for the FDA staff who does not normally visit manufacturing companies.

#### 2. What did you like least about the course?

- Most of the participants answered “None”.

- The length of the course is too short.
- The involvement of the manufacturing company in providing lectures for process validation because this type of lecture should be provided only by 3<sup>rd</sup> party Non-Philippine FDA related entity.
- Plant visit is specifically for the overview of their facilities, not for lectures and auditing. It is not the proper venue for DRA to comment and evaluate their own documents at their own site for this kind of training/event.

**3. What are your recommendations/suggestions for improvement of the course?**

- For future trainings, kindly include validation and qualification of water system, air handling, and analytical method, biological.
- To give recommendation to FDA management to revise the guidelines as to acceptance, review and approval of process validation protocols and reports
- Additional case studies (good process validation report) with a comparison of good and bad dossiers.
- Images of machines/equipment's should also be presented (photo/picture) during the training for much appreciation of the discussion and brighten the power point presentation.
- Longer duration of time allotted for the topics to avoid saturation of ideas during discussion. Lengthen the training course from 4 to 5 days.

<b>NATIONAL CONSCIOUSNESS WEEK AGAINST COUNTERFEIT MEDICINES</b>	
Acacia Hotel Manila, Filinvest Corporate City Alabang Muntinlupa City, 1781, Philippines	
November 19, 2012	
<b>PROGRAM OF ACTIVITIES</b>	
8:30 – 9:00	Registration: <b>Adrianita Castillo (Admin Dept.)</b> <b>Merlita Pedron (PPAD)</b> <b>PAPPI</b>
9:00 – 9:15	National Anthem/ Invocation Welcome Remarks: <b>Atty. Emilio L. Polig, Jr.</b> Chief, Legal Information and Compliance Division (LICD) Introduction of Keynote Speaker
9:15 – 9:30	Keynote Speaker: <b>Kenneth Y. Hartigan-Go, MD</b> Acting Director IV, FDA
9:30 – 10:30	Declaration of Support Against Counterfeit Drugs: <b>DepEd/ DILG/ DOJ/ DTI/ BOC/ IPOP/HL/ NBI/ PNP/ League of Cities/ PIA/ Office of the Mayor Muntinlupa City</b>
10:30 – 10:45	Coffee Break
10:45 – 11:45	Introduction of Guest Speaker: <b>Nemia T. Getes</b> Chief, Regulation Division I Guest Speaker: <b>Souly Phanouvong, Pharm.D., Ph.Ds.</b> Manager, Asia Programs, USP PQM Open Forum
11:45 – 12:00	Closing Remarks: <b>Atty. Emilio L. Polig, Jr.</b> Chief, Legal Information and Compliance Division (LICD)



Dr. Souly Phanouvong speaks at the Philippines FDA's "National Consciousness Week against Counterfeit Medicines"



**MINUTES OF ADDITIONAL MEETINGS**

**Date:** November 19, 2012  
**Time:** 1:30 PM – 3:00 PM  
**Venue:** Acacia Hotel Manila, Filinvest Corporate City, Alabang, Muntinlupa City  
**Attendees:** Dr. Souly Phanouvong (PQM), Maria Kathrina Olivarez (PQM), Maria Lourdes Santiago (FDA), Jocelyn Balderrama (FDA), Virginia Francia Laboy (FDA) and Nemia Getes (FDA).  
**Subject:** PQM Workplan activities and changes at FDA office in 2013

Activity/Issues/Concerns	Action Items/ Comments
<ul style="list-style-type: none"> <li>FDA Philippines will be divided in (4) Centres'</li> </ul>	<ul style="list-style-type: none"> <li>Center for Drugs</li> <li>Center for Foods</li> <li>Center for Cosmetics</li> <li>Center for Medical Devices</li> <li>Beginning January 2013 Maria Lourdes Santiago will be the Chief, Center for Drugs and Jocelyn Balderrama will now be the Chief, Laboratory Services Division.</li> <li>No formal memo yet for this arrangement. FDA is still waiting for document to be signed. This change will run for 6 months and then evaluated if the change was effective.</li> </ul>
<ul style="list-style-type: none"> <li>Center for Drugs</li> </ul>	<ul style="list-style-type: none"> <li>Licensing and Registration</li> <li>Product Research</li> <li>Laboratory</li> </ul>
<ul style="list-style-type: none"> <li>International Affairs</li> </ul>	<ul style="list-style-type: none"> <li>This will be the single entry point of contact for all international and domestic activities.</li> <li>This will be the new office of USP PQM program and the country consultant will report directly to the FDA Director and Chief of International Affairs.</li> <li>The Center for Drugs will always be of help with USP PQM.</li> <li>A brief background presentation of the PQM program and FY13 Workplan will be presented to Dr. Kenneth Hartigan-GO (Acting Director IV, FDA) and Virginia Francia Laboy (Chief, International Affairs).</li> </ul>
<ul style="list-style-type: none"> <li>BA/BE training</li> </ul>	<ul style="list-style-type: none"> <li>FDA suggested the participation of Dr. Vinod Shah for the lecture and hands on training.</li> <li>Looking at the regulatory perspective</li> </ul>
<ul style="list-style-type: none"> <li>Regional Field Office (RFO)</li> </ul>	<ul style="list-style-type: none"> <li>Expansion of the 2<sup>nd</sup> line ATBs for MQM – expand the number of drugs to be tested and still focus on the 8 Sentinel Sites.</li> </ul>
<ul style="list-style-type: none"> <li>Newly added (2) Sentinel Sites</li> </ul>	<ul style="list-style-type: none"> <li>How effective they are in terms of strengthening MQM and if they have technical or financial gaps.</li> <li>FDA wants the project to be sustainable and they always offer cost sharing with the project.</li> </ul>

<ul style="list-style-type: none"> <li>60,000 number of registered medicines</li> </ul>	<ul style="list-style-type: none"> <li>They are registered based on the generic name.</li> <li>An Administrative Order (AO) was released under the former Secretary of Health, Esperanza Cabral to limit the number of pharmaceutical products based on its formulation; however this is not implemented due to political issues.</li> </ul>
<ul style="list-style-type: none"> <li>Co-share and include anti-malarial and ARVs to MQM</li> </ul>	<ul style="list-style-type: none"> <li>Yes, FDA is capable but need to consider the availability of the reference standards.</li> <li>Need to request from DOH a list from their International donors since anti-malarial and ARVs are being donated to the Philippines.</li> <li>Need information to when, where and which site it was delivered.</li> </ul>
<ul style="list-style-type: none"> <li>Capacity building</li> </ul>	<ul style="list-style-type: none"> <li>The Davao Sat lab is for the Mindanao Region and the Cebu Sat lab is for the Visayan Region</li> <li>Davao is the top priority for capacity building since they are more ready and will process ISO accreditation this year.</li> <li>However, Cebu will follow because as of the moment there will be infrastructure improvements at the laboratory.</li> </ul>
<ul style="list-style-type: none"> <li>FDA central lab for WHO Pre-Qualifications (WHO PQ)</li> </ul>	<ul style="list-style-type: none"> <li>Focal person, Catherine Dauphin left WHO and as a protocol they cannot go directly to WPRO.</li> <li>FDA does not have any update or feedback about WHO PQ.</li> </ul>
<ul style="list-style-type: none"> <li>Enforcement</li> </ul>	<ul style="list-style-type: none"> <li>With the changes at FDA, Atty. Donna Mae Sanchez will be the future Officer-in-Charge of the Regulatory Enforcement Unit (REU) Head and will work closely with RHO and Atty. Emilio L. Polig, Jr., Chief, Legal Information and Compliance Division (LICD)</li> <li>FDA is interested to participate: Building Regional Expertise in Medicine Regulation, Information Sharing, Joint investigation and Enforcement (BREMERE)</li> </ul>
<ul style="list-style-type: none"> <li>National Consciousness Week Against Counterfeit Medicines</li> </ul>	<ul style="list-style-type: none"> <li>On June 15, 2012, it was declared by the President of the Philippines under proclamation no. 2082 that the Third week of November of Every Year as the “National Consciousness Week Against Counterfeit Medicines”.</li> </ul>
<ul style="list-style-type: none"> <li>Technical Alliance Program (TAP)</li> </ul>	<ul style="list-style-type: none"> <li>FDA Philippines a very good candidate for the program.</li> <li>Need to pass WHO classification to get 75% discount on USP RF procurement.</li> <li>TAP can help on purchasing reference standards for government laboratories.</li> </ul>
<ul style="list-style-type: none"> <li>Network for Official Medicine Control Laboratories (NOMCOL) Asia</li> </ul>	<ul style="list-style-type: none"> <li>Targets are Asian countries however excluding India.</li> <li>May also expand to the Western Pacific Region to cover Solomon Island and Papua New Guinea.</li> <li>FDA is suggested to express their interested to join.</li> <li>All interested official laboratories can participate in NOMCOL Asia even if they do not have WHO PQ.</li> </ul>

**Date:** November 20, 2012  
**Time:** 1:30 PM – 3:00 PM  
**Venue:** FDA, Conference Room, Filinvest Corporate City, Alabang, Muntinlupa City  
**Attendees:** Dr. Souly Phanouvong (PQM), Maria Kathrina Olivarez (PQM), Jocelyn Balderrama (FDA), Haydee Guanio (FDA), Gilbert Vargas (PASCUAL), Helen Tanwangco (INTERPHIL), Maria Aileen Manalang (INTERPHIL), Lucita Soriano (HIZON), Lillibeth Escueta (AMHERST), Nestor Mendoza (LLYOD), Dolora Cardinal (LLYOD) and Isagani Ocampo (SCHEELE).  
**Subject:** Meeting with the Pharmacy Industry and potential 2<sup>nd</sup> line TB Manufacturers and to follow-up those had interest on the WHO PQ in the Philippines.  
**Objectives:** For the Filipino manufacturers producing SL-ATBs to receive assistance from the USP PQM towards the WHO PQ. The TS is free of charge, this is funded by the USAID. The priority list of ATBs of high interest for TS is as below:

1. Amikacin, solution inj. 500 mg/2 ml vial, amp; powder for inj. 1g vial, amp
2. Capreomycin, powder for injection 1g, vial
3. Cycloserine, capsule 250 mg
4. Ethionamide, tablet /capsule 250 mg
5. Kanamycin, powder for injection 1g, vial
6. Kanamycin, powder for injection 500 mg, vial
7. Levofloxacin, tablet /capsule 250 mg, tablet 500 mg, tablet 750 mg
8. Moxifloxacin, tablet /capsule 400 mg
9. Ofloxacin, tablet /capsule 200 mg; 400 mg
10. Prothionamide, tablet /capsule 250 mg
11. Para-Aminosalicylic Acid (PAS) sachets, 4 g granules
12. PAS Sodium 100 g jar granules, 4g / 9.2 g sachets granules; powder for oral solution sachets
13. Terizidone, tablet/capsule, 250 mg; 300 mg

Activity/ Issues/Concerns	Action Items/ Comments
<ul style="list-style-type: none"> <li>• 5<sup>th</sup> Annual Prequalification of Medicines Programme (PQP) Assessment Training</li> </ul>	<ul style="list-style-type: none"> <li>• At least 2 FDA staff to participate in Copenhagen, Denmark on March 13-16, 2013.</li> <li>• Focus on Quality Aspects in the Assessment of a Generic Product Dossier, Bioequivalence and Biowaiver Issues, Product Information and Labeling.</li> </ul>
<ul style="list-style-type: none"> <li>• WHO PQ Overview</li> <li>• Technical Support from PQM</li> </ul>	<ul style="list-style-type: none"> <li>• A questionnaire will be given to the pharmaceutical manufacturers to facilitate the process of evaluating pharmaceutical manufacturers interested in receiving technical assistance.</li> <li>• The Management should have the political will and commitment to complete WHO PQ.</li> <li>• PQM does not approve the application; they only support to check the completeness and quality of the dossier before submission.</li> <li>• Upcoming training in Jakarta, Indonesia on March 2013.</li> </ul>
<ul style="list-style-type: none"> <li>• WHO PQ</li> </ul>	<ul style="list-style-type: none"> <li>• Express interest.</li> </ul>

Requirements	<ul style="list-style-type: none"> <li>• Submit the dossier.</li> <li>• Once the dossier was approved, the manufacturing company will be scheduled for inspection by WHO.</li> <li>• The audit will usually take 2-3 days depending on the facility/ production area.</li> <li>• It will take 4-6 weeks to receive feedback from the auditors.</li> <li>• If there will be any critical findings, the auditors need to go back to the plant for another inspection.</li> </ul>
<ul style="list-style-type: none"> <li>• Time frame for the submission of the WHO PQ Questionnaire.</li> </ul>	<ul style="list-style-type: none"> <li>• Agreed to accomplish on or before December 7, 2012.</li> </ul>
<ul style="list-style-type: none"> <li>• FDA Philippines</li> </ul>	<ul style="list-style-type: none"> <li>• Need to make sure that they can handle to come for an inspection/ observations with WHO.</li> <li>• Build support mechanism with the companies.</li> <li>• Engage and collaborate with FDA inspectors.</li> </ul>

**Date:** November 21, 2012

**Time:** 1:30 PM – 3:00 PM

**Venue:** WPRO Office, United Nations Ave. Manila, Philippines

**Attendees:** Dr. Souly Phanouvong (PQM), Maria Kathrina Olivarez (PQM), Dr. Klara Tisocki (WPRO), Dr. Eva Maria Christophel (WPRO) and Dr. Bayo Fatunmbi (WPRO).

**Subject:** PQM Philippines update and to explore collaboration opportunities in the areas of Medicine Quality in view of the new development of AusAid new commitments in the Asia-Pacific Region on Malaria

Activity/ Issues/Concerns	Action Items/ Comments
<ul style="list-style-type: none"> <li>• Strengthening the capacity of regulatory authorities for product evaluation and Post Marketing Surveillance (PMS).</li> </ul>	<ul style="list-style-type: none"> <li>• The PMS is to train the monitoring system at the field level.</li> <li>• The comparative study started 2 weeks ago in Laos, Cambodia, Myanmar and Thailand and should be complete in June 2013.</li> <li>• The comparative study aim to collect randomly from the samples from the MQM supported sites versus the non-sentinel sites.</li> </ul>
<ul style="list-style-type: none"> <li>• Raising awareness for counterfeit medicines.</li> </ul>	<ul style="list-style-type: none"> <li>• PQM team participated in the Philippines FDA National Consciousness Week Against Counterfeit Medicines.</li> <li>• PQM set up a booth and presented a photo exhibit “Pharmacide Arts” for public viewing.</li> </ul>
<ul style="list-style-type: none"> <li>• Global Alert System</li> </ul>	<ul style="list-style-type: none"> <li>• Drug regulators’ and authorities are reporting.</li> <li>• 10 countries (such as Vietnam, Cambodia, Philippines, Malaysia and Indonesia) are already participating.</li> <li>• Pilot testing is scheduled to happen on January 2013.</li> </ul>

<ul style="list-style-type: none"> <li>Recently found suspected counterfeit medicine: Co-Artem</li> </ul>	<ul style="list-style-type: none"> <li>USP has already notified the relevant officers/ investigators of both PMI and GFATM about this product details. Feedback will be shared to WHO and WPRO for advice and next steps.</li> </ul>
<ul style="list-style-type: none"> <li>PQM Philippines Update</li> </ul>	<ul style="list-style-type: none"> <li>PQM Philippines Fact Sheet was presented to the group for reference.</li> <li>The program covers ATBs medicines and proposes in expanding to Anti-malaria's and ARVs.</li> </ul>
<ul style="list-style-type: none"> <li>Building Regional Expertise in Medicine Regulation, Information Sharing, Joint investigation and Enforcement (BREMERE)</li> </ul>	<ul style="list-style-type: none"> <li>Philippines and Indonesia are associate members.</li> <li>Another meeting will be held in Cambodia on February 2013.</li> <li>The WHO roles in BREMERE are for technical support, context of SSFFC and get more clarity for the new alert system.</li> <li>Draft TOR will be forwarded to WPRO for advice and comments.</li> </ul>
<ul style="list-style-type: none"> <li>Potential collaboration with AusAid and WHO</li> </ul>	<ul style="list-style-type: none"> <li>Collaboration with WHO; the training of FDA staff and MQM expansion to Anti-biotics.</li> <li>WHO PQM Countries: Vietnam and Singapore</li> <li>WHO PQM laboratories should be functional and the countries participating to PQ should show commitment.</li> </ul>

**Date:** November 21, 2012

**Time:** 4:30 PM – 6:00 PM

**Venue:** Manila Pavillion Hotel, United Nations Ave. Ermita, Manila, Philippines

**Attendees:** Dr. Souly Phanouvong (PQM), Maria Kathrina Olivarez (PQM), Dr. Leonel Santos (USP) Dean Imelda Peña (U.P. Manila, College of Pharmacy/ NIH/ IPS), Joanna Toralba (U.P. Manila, College of Pharmacy), Bryan Paul Bulatao (U.P. Manila, College of Pharmacy), Dr. Erna Arollado (NIH/ IPS), Vina Rose Dahilig (NIH/ IPS), Dean Peralta Crucis (Adamson University, College of Pharmacy), Dr. Belinda Conde (Adamson University, College of Pharmacy), Marylyn Ngo (University of Sto. Tomas, College of Pharmacy), Olivia Limuaco (Centro Escolar University, College of Pharmacy) and Lilibeth Escueta (QA Regulatory Manager, Amherst Lab, Inc.)

**Subject:** Meeting with U.P. Manila and selected BA/BE Centers in the Philippines.

**Objectives:** Explore a potential institution with expertise and capacity in conducting BE studies for ATBs that may be interested in joining the ANEQAM. Identify the BA/BE centers with potential and strong interest in improving their expertise and skills and operations towards WHO acceptance and conduct BE studies to clients in the region with competitive fees and services

Activity/ Issues / Concerns	Action Items/ Comments
<ul style="list-style-type: none"> <li>BA/BE Centre's in Southeast Asia</li> </ul>	<ul style="list-style-type: none"> <li>Looking for 2 centre's that can operate under the International</li> </ul>

	<p>Standards (WHO requirements).</p> <ul style="list-style-type: none"> <li>Philippines have a good potential for BA/BE.</li> </ul>
<ul style="list-style-type: none"> <li>Technical assistance to be provided for the BA/BE Studies</li> </ul>	<ul style="list-style-type: none"> <li>Train the centre for GMP and GLP.</li> <li>Need to use the product list of WHO and the protocol has to be comparable with WHO requirements.</li> </ul>
<ul style="list-style-type: none"> <li>BA/BE challenges: <ul style="list-style-type: none"> <li>Financial resources</li> <li>The search for the funding source will be a great challenge for the Universities since PQM will only provide technical assistance.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Initiate discussion and collaboration with the industry (PCPI and PACOP), government agencies (DOST, PCARD and FDA) and hospitals.</li> <li>Create a concept paper/document to support the project.</li> </ul>