

Workshops on Establishing a Medicine Quality Monitoring Program and Applying Full Compendial Testing Methods to Evaluate the Quality of Anti-TB medicines

Jakarta, Indonesia
June 11-18, 2012

Trip Report

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PROMOTING THE QUALITY OF MEDICINES

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Executive Summary

PQM staff, along with Dr. Richard Jähnke of Global Pharma Health Fund (GPHF), conducted two workshops in Jakarta, Indonesia for staff from the National Quality Control Laboratory on Drug and Food (NQCLDF) and the Provincial Quality Control Laboratory on Drug and Food (PQCLDF) June 11-18, 2012. The trainings covered:

- Establishing a medicines quality monitoring (MQM) program, including basic testing, sampling procedures, data management and reporting for anti-tuberculosis (TB) medicines and essential antibiotics in Indonesia
- Full compendial testing methods to evaluate the quality of first- and second-line anti-TB medicines

The trainings involved presentations and hands-on practice on each of the subjects. At the end of workshop, action plans were developed by the workshop participants to lay out key steps that each of the involved parties will need to take to implement the projects in Indonesia.



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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, PMI or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- Drs. Syamsudin, MSi, Apt, Director of NQCLDF of NA- DFC, Republic Indonesia
- Dra. Agustine Zaini, Director, Standardization of Therapeutic Products & Household Products of NA-DFC, Republic Indonesia
- Dra. Ati Setiawati, Apt, Chief of NQCL DF of NA-DFC, Republic Indonesia
- Drg. Dyah Erti Mustikawati, MSc., Manager/Head of Sub-directorate Tuberculosis Directorate General Disease Control & Environmental Health, Ministry of Health of Republic Indonesia
- All of the training participants from NQCLDF and PQCLDF, the heads of the provincial sites, and the investigators and laboratory technicians for their kindness and support in providing their laboratories for use and coordinating the trainings.
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- Dr. Richard Jähnke, GPHF Project Manager, for his expertise and assistance
- PQM's administrative and editorial staff for their support

ACRONYMS

DQI	Drug Quality and Information Program
BADAN POM or NA-DFC	Indonesia National Agency for Drug and Food Control
CPMT	Central Project Management Team
NQCLDF	National Quality Control Lab for Drugs and Food
PQCLDF	Provincial Quality Control Lab for Drugs and Food
FDC	Fixed Dose Combination
GPHF	Global Pharma Health Fund
HPLC	High Performance Liquid Chromatography
MOH	Ministry of Health
PQM	Promoting the Quality of Medicines Program
PSIT	Provincial Site Implementation Team
PVT	Performance Verification Test
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
TB	Tuberculosis
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia

Background

With a population of 231 million, Indonesia carries the third highest TB burden globally and faces the challenge of multi-drug resistance to anti-TB medicines. The treatment, according to the National TB Program, is based on World Health Organization (WHO) guidelines and uses RHZE FDC4 (Rifampicin 150 mg, Isoniazid 75 mg, Pyrazinamide 400 mg, Ethambutol 275 mg) and RH FDC2 (Rifampicin 150 mg, Isoniazid 150 mg) as first-line tuberculosis (TB) drugs; for second-line, the National TB Program uses mostly Kanamycin, which is procured from WHO prequalified sources outside of the country, using resources from the Global Fund.

Purpose of Trip

The PQM team traveled to Indonesia to conduct two trainings for staff from the National Quality Control Lab for Drugs and Food (NQCLDF) and Provincial Quality Control Lab for Drugs and Food (PQCLDF):

- Establishing a medicine quality monitoring (MQM) program in selected provincial sites
- Compendial analysis to evaluate the quality of first- and second-line anti-TB medicines

Overview of Activities

Final training preparations: June 8-9, 2012

PQM staff met with Drs. Syamsudin, MSi, Apt, and Dra. Ati Setiawati, Apt, the senior management team of BADAN POM—also known as the Indonesia National Agency of Drug and Food Control (NA-DFC)—to update each other on the training preparations and to identify and address any outstanding issues relevant to trainings. The group worked together to set up work stations, prepare all necessary supplies, and verify all other logistics.

Training 1: Establishing an MQM program for anti-TB medicines in selected provincial sites in Indonesia (June 11-16, 2012)

Item	Description
Specific Objectives/ Expected Outcomes	Objective: Train Indonesia staff to conduct an MQM program Expected Outcome: Staff will be able to – <ul style="list-style-type: none">○ analyze medicines using the Minilab®○ generate reliable result reports○ maintain MQM activities to strengthen post-marketing surveillance
Venue/Location	NQCLDF, Jakarta
Organizers	PQM, GPHF, and Indonesia NQCLDF of NA-DFC
Sponsors	USAID/Indonesia (through PQM) and Indonesia NA-DFC
Trainers and Facilitators	<ul style="list-style-type: none">○ Souly Phanouvong, PQM○ Yanga K Dijiba, PQM○ Mark Liddell, USP○ Elaine Yuan, PQM○ Richard Jähnke, GPHF
Trainees	29 staff participated in the training. See Participant List in Annex 1 for detailed information.
Agenda	See Agenda in Annex 2 for detailed information.

Opening Ceremony	See Annex 3 for detailed information.
Modules	<ul style="list-style-type: none"> ○ GPHF – The impact of poor quality medicines (Theory) ○ Introduction to Basic Tests (Presentation) ○ Thin-Layer Chromatography (TLC) (Presentation and Hands-on) ○ Physical/Visual Inspection (Presentation and Hands-on) ○ Simple Disintegration (Presentation and Hands-on) ○ Sampling Procedures (Presentation and Discussion) ○ Next Steps (Presentation and Discussion) ○ Use of Minilab[®] (hands-on) – Simple Disintegration, Physical/Visual Inspection and TLC
Closing Ceremony	<ul style="list-style-type: none"> ○ Dr. Souly Phanouvong, PQM ○ Dr. Richard Jähnke, GPHF ○ Dra. Ati Setiawati, NQCLDF ○ Certificates awarded
Equipment Provided	<ul style="list-style-type: none"> ○ Five new Minilabs[®] were procured for selected PQCLDF sites (East Java–Surabaya, South Sulawesi-Makasar, West Nusa Tenggara-Mataram, Banten-Serang, and North Sumatra-Medan) to establish an MQM program in Indonesia. ○ Reference standards (RS), columns, lab reagents and supplies ○ Training supplies (lab coats, gloves, glasses, aprons, stationery)
Training Evaluation	All participants agreed that the training was useful and will help them perform their jobs better. See participant evaluations of the training course in Annex 4 .
Outcomes/ Conclusion	<ul style="list-style-type: none"> ○ Training on all modules was completed. All objectives and expected outcomes were met. ○ The participants made crucial contributions to the development of an MQM protocol document, which will ensure the implementation of a robust program
Next Steps	<p>The plan for the next steps was formed by the participants to ensure MQM will be carried out properly:</p> <ul style="list-style-type: none"> ○ Finalize the formation of a central project management team (CPMT) to lead and coordinate the program and dispatch the funds to provinces for program implementation ○ Finalize the formation of a provincial site implementation team (PSIT) for each site. Each team will have the responsibility of drafting itemized budgets for implementing MQM activities for their site, allocating space for their Minilab[®], receiving funds from the CPMT, assigning staff to specific MQM activities, and communicating with and reporting to the CPMT with technical and programmatic issues in a timely manner



Photos of the participants and trainers taken during the MQM training



Training 2: Training Workshops on Quality of Anti-Tuberculosis Medicines, Evaluation of the Quality of 1st and 2nd Line Anti-Tuberculosis Medicines by Full Compendial Testing Method (June 11-18, 2012)

Item	Description
Specific Objectives/ Expected Outcomes	<p>Objective:</p> <ul style="list-style-type: none"> ○ Train participants on the following techniques: Dissolution and its Performance Verification Test (PVT), HPLC method of analysis, and UV-Vis. ○ Train participants on proper use of the compendial method for the analysis of 1st and 2nd line anti-tuberculosis medicines ○ Train participants on Good Laboratory Practices when analyzing anti-tuberculosis medicines <p>At the end of the training, participants will be able to:</p> <ul style="list-style-type: none"> ○ Understand the importance and requirements of each technique. ○ Properly use each technique and adhere strictly to its system suitability. ○ Be able to use compendial methods HPLC, UV, and Dissolution to evaluate the quality of anti-tuberculosis medicines ○ Be able to interpret the data from the analyses
Venue/Location	National Quality Control Laboratory of Food and Drug, Jakarta, Indonesia
Organizers	PQM, NQCLDF
Sponsors	USAID/Indonesia, through PQM, and NAD-FC
Trainers and Facilitators	<ul style="list-style-type: none"> ○ Yanga K Dijiba, PQM ○ Mark Liddell, USP ○ Elaine Yuan, PQM ○ Souly Phanouvong, PQM ○ Richard W. O. Jähnke, GPHF
Trainees	16 staff participated in the training. See Participant List in Annex 5 for detailed information.
Agenda	See Agenda in Annex 6 for detailed information.
Modules	<p>Training modules were completed on:</p> <ul style="list-style-type: none"> ○ Dissolution ○ Dissolution PVT ○ HPLC ○ UV
Closing Ceremony	<ul style="list-style-type: none"> ○ Dr. Yanga K. Dijiba, PQM ○ Dra. Ati Setiawati, Apt, NQCLDF ○ Certificates provided
Standard and Equipment Provided	<ul style="list-style-type: none"> ○ Standards for all the monographs discussed were provided by USP/PQM but they were not cleared through customs in time. ○ Training supplies (lab coats, gloves, glasses)
Training Evaluation	All participants agreed that the training was useful and will help them perform their jobs better. See participant evaluations of the training course in Annex 7 .

Outcomes/Conclusion	<ul style="list-style-type: none"> ○ Training on all modules was completed. All objectives and expected outcomes were met.
Next Steps	<ul style="list-style-type: none"> ○ Redo the PVT for the failed PVT of apparatus 2 (paddles) and submit the calculation results to PQM for review ○ Redo the rifampin test following the instructors' advice to obtain good results ○ Test additional anti-TB samples using pharmacopeial monographs and consult with PQM if difficulties arise ○ Conduct additional tests, review the data from the provincial laboratory, and communicate with PQM for any needed help.



Photos of the participants and trainers taken during the Compendial Testing training



List of Attendance for Participants
Training on Establishing Anti-TB Medicines Quality Monitoring: Basic Tests, Sampling Procedures, Data Management and Reporting

No	Name	Institution/Unit	Position
1	Drs. I Nyoman Sumasada, Apt.,MH	PQCLDF at Serang	Head of PQCLDF
2	Dra. Endang Pudjiwati,Apt.,MM	PQCLDF at Surabaya	Head of PQCLDF
3	Dra. Sri Utami Ekaningtyas, Apt.MM	PQCLDF at Mataram	Head of PQCLDF
4	Drs.Muh.Guntur,Apt.,M.Kes	PQCLDF atMakassar	Head of PQCLDF
5	Drs. Juli H Napitupulu, Apt	PQCLDF at Medan	Head of PQCLDF
6	Drs. Supriyanto Utomo, M.Kes,Apt	PQCLDF at Semarang	Head of PQCLDF
7	Drs. Wusmin Tambunan, Apt.,M.Si	PQCLDF at Bandung	Head of PQCLDF
8	Dra. Zulaimah, Apt.,M.Si	PQCLDF at Yogyakarta	Head of PQCLDF
9	Drs. Indra Ginting,Apt.MM	PQCLDF at Padang	Head of PQCLDF
10	Dra. Corry Panjaitan,Apt	PQCLDF at Denpasar	Head of PQCLDF
11	Devana Ardiaty,S.Farm,Apt	PQCLDF at Serang	Investigation staff
12	Vannina Agustyani,S.Farm.,Apt	PQCLDF at Surabaya	Investigation staff
13	Yogi Abaso Mataram, S.Si.,Apt	PQCLDF at Mataram	Investigation staff
14	Drs. Muhammad Ridwan, Apt	PQCLDF at Makassar	Investigation staff
15	Dra. Ratna Siregar M.Si, Apt	PQCLDF at Medan	Investigation staff
16	Eny Suryani,S.Farm.,Apt	PQCLDF at Serang	Laboratory staff
17	Hening Setyawati,S.Farm.,Apt	PQCLDF at Serang	Laboratory staff
18	Ervin Usnanik, S.Si	PQCLDF at Surabaya	Laboratory staff
19	Rini Wulansari, S.Si.,Apt	PQCLDF at Surabaya	Laboratory staff
20	Yuyun Wijayanti, S.Si.,Apt	PQCLDF at Mataram	Laboratory staff
21	Atika Andriani, A.Md	PQCLDF at Mataram	Laboratory staff
22	Ana Adriyani,S.Si.,Apt	PQCLDF at Makassar	Laboratory staff
23	Muriany Faisal, S.Si.,Apt	PQCLDF at Makassar	Laboratory staff
24	Dewi Afriani S.Si.,Apt	PQCLDF at Medan	Laboratory staff
25	Yuni Elvina	PQCLDF at Medan	Laboratory staff
26	Sri Nurhayati.S.Si.,Apt	CRDF-NADFC	Laboratory staff
27	Nur Istifaiyah,A.Md	NQCLDF	Laboratory staff
28	Abdullah,A.Md	NQCLDF	Laboratory staff
29	Devi Astuti	NQCLDF	Laboratory staff

Tentative Agenda

Establishing Medicines Quality Monitoring: Basic Tests, Sampling Procedures, Data Management and Reporting

Jakarta, Indonesia

June 11-15, 2012

Day/Time	Topic/Activity	Presenter/Facilitator
Day 1		
8:30 – 9:00 am	Registration	
9:00 – 9:45 am	<ul style="list-style-type: none"> • Welcome remarks 	NQCL-DF, USAID, NTP, USP PQM
	<ul style="list-style-type: none"> • Introduction: Objectives and expected outcomes of training and program • Self-introduction of participants, facilitators, and trainers 	Souly Phanouvong All
9:45 – 10:00 am	<i>Morning Tea/Coffee break</i>	
10:00 – 12:00 pm	Presentations <ul style="list-style-type: none"> • Counterfeit medicines and use of Minilab[®] • Introduction to QA and GLP • Principles of GLP – Minilab[®] 	Richard Jähnke (GPHF) Souly Phanouvong (PQM) Souly Phanouvong
12:00 – 1:00 pm	<i>Lunch</i>	
1:00 – 2:30 pm	Presentations <ul style="list-style-type: none"> • Introduction to Basic Tests • Physical/Visual Inspection • Simple Disintegration test 	Souly Phanouvong Richard Jähnke
2:30 – 2:45 pm	<i>Afternoon Tea</i>	
2:45 – 5:00 pm	Presentations <ul style="list-style-type: none"> • Thin Layer Chromatography (TLC) • Minilab[®] Safety Measures Hands-on training <ul style="list-style-type: none"> • Pipetting and Spotting Practice 	Richard Jähnke Souly Phanouvong Participants
Day 2		
9:00 – 10:30 am	<ul style="list-style-type: none"> • Review of Day 1 Hands-on training <ul style="list-style-type: none"> • TLC - levofloxacin tablets 	Elaine Yuan (PQM) Richard Jähnke/Participants
10:30 – 10:45	<i>Morning Tea</i>	

<i>am</i>		
10:45 – 12:00 pm	Hands-on training <ul style="list-style-type: none"> • Minilab[®] analysis of levofloxacin tablets 	Richard Jähnke/Participants
12:00 – 1:00 pm	<i>Lunch</i>	
1:00 – 2:30 pm	Hands-on training <ul style="list-style-type: none"> • TLC - Prothionamide tablets 	Souly Phanouvong/Participants
2:30 – 2:45 pm	<i>Afternoon Tea</i>	
2:45 – 5:00 pm	Hands-on training <ul style="list-style-type: none"> • TLC - Moxifloxacin tablets 	Richard Jähnke/Participants
Day 3		
9:00 – 10:30 am	<ul style="list-style-type: none"> • Review of Day 2 Hands-on training <ul style="list-style-type: none"> • TLC - Cefixime tablets 	Souly Phanouvong Richard Jähnke/Participants
10:30 – 10:45 am	<i>Morning Tea</i>	
10:45 – 12:00 pm	Hands-on training <ul style="list-style-type: none"> • Disintegration - Cefixime tablets 	Richard Jähnke/Participants
12:00 – 1:00 pm	<i>Lunch</i>	
1:00 – 2:30 pm	Hands-on training <ul style="list-style-type: none"> • TLC - rifampicin/isoniazid FDC Tablets 	Souly Phanouvong/Participants
2:30 – 2:45 pm	<i>Afternoon Tea</i>	
2:45 – 5:00 pm	Hands-on training <ul style="list-style-type: none"> • TLC - rifampicin/isoniazid FDC Tablets, cont'd 	Participants
Day 4		
9:00 – 10:30 am	<ul style="list-style-type: none"> • Review of Day 3 • Discussion of Day 3 Results Hands-on training <ul style="list-style-type: none"> • Minilab[®] analysis of rifampicin/isoniazid/pyrazinamid/ethambutol FDC tablet 	Elaine Yuan Richard Jähnke /Souly Phanouvong Richard Jähnke
10:30 – 10:45 am	<i>Morning Tea</i>	
10:45 – 12:00 pm	Hands-on training <ul style="list-style-type: none"> • Minilab[®] analysis of rifampicin/isoniazid/pyrazinamid/ethambutol FDC tablet, cont'd 	Richard Jähnke /Participants
12:00 – 1:00 pm	<i>Lunch</i>	
1:00 – 2:30 pm	Presentation <ul style="list-style-type: none"> • Sampling protocol 	Souly Phanouvong

2:30 – 2:45 pm	<i>Afternoon Tea</i>	
2:45 – 5:00 pm	Preparation for individual test of samples <ul style="list-style-type: none"> • Each participant will receive one sample by chance/draw 	Participants
Day 5		
9:00 – 10:30 am	<ul style="list-style-type: none"> • Review of Day 4 Hands-on training <ul style="list-style-type: none"> • Individual Minilab[®] analysis of chosen product sample (physical/visual inspection, disintegration, and TLC, with report form completed) 	Elaine Yuan Participants
10:30 – 10:45 am	<i>Morning Tea</i>	
10:45 – 12:00 pm	Hands-on training <ul style="list-style-type: none"> • Individual Minilab[®] analysis of sample 	Participants
12:00 – 1:00 pm	<i>Lunch</i>	
1:00 – 1:30 pm	<ul style="list-style-type: none"> • Individual sample test evaluation 	Souly Phanouvong
1:30 – 2:30 pm	Presentations <ul style="list-style-type: none"> • Next Steps 	Souly Phanouvong
2:30 – 2:45 pm	<i>Afternoon Tea</i>	
2:45 – 5:00 pm	<ul style="list-style-type: none"> • Review of Training • Questions/Discussion Closing Ceremony <ul style="list-style-type: none"> • Conclusion of Trainings • Presentation of Certificates • Final Words 	Souly Phanouvong All NQCL-DF Director, GPHF, USP PQM All All

OPENING CEREMONY

“Training on Establishing Anti-TB Medicines Quality Monitoring: Basic Tests, Sampling Procedures, Data Management and Reporting” and “Training on Compendial Analysis of TB Medicines”

Jakarta, June 11 2012
Acacia Hotel, Room Rose I

Time	Activities	Speaker/Facilitator
8.00 - 9.00 WIB	Registration	Committee
9.00 - 9.03 WIB	Welcome speech	Committee
9.03 - 9.10 WIB	Report speech from Head of Therapeutic Product and Hazardous Substances Division	Dra. Ati Setiawati, M.Si
9.10 - 9.20 WIB	Opening speech from Head of NQCLDF	Drs. Syamsudin, M.Si
9.20 - 9.25 WIB	Speech from Manager of Asia Programs, Promoting the Quality of Medicines Program (PQM) USP	Souly Phanouvong, PharmD, PhD
9.25 - 9.30 WIB	Speech from Senior Infectious Disease Advisor, Office of Health-USAID	Dr. Kendra Chittenden, PhD
9.30 - 9.35 WIB	Speech from Head of Sub-directorate TB MoH	Drg. Dyah Erti Mustikawati, M.Sc
9.35 - 9.40 WIB	USAID hands over the Minilabs and other training supplies to the Head of NQCLDF	Drs. Syamsudin, M.Si Dr. Kendra Chittenden, PhD
9.40 - 9.45 WIB	Photo session	All
9.45 - 10.00 WIB	Coffee/tea break	All
	After coffee/tea break, participant divided in two group	Committee
	1. Group of Training Establishing Anti-TB Medicines Quality Monitoring	
	2. Group of training Compendia Analysis	
	Introduction of the Workshop	Souly Phanouvong, PharmD, PhD

Evaluations by Participants
 PQM Training Workshops
 Establishing Medicines Quality Monitoring
 for Anti-TB Medicines
 Basic Tests, Sampling Procedures and Drug Management and Reporting

Jakarta, Indonesia June 11-15, 2012

Overall Evaluation of the Training Workshop

	Strongly agree	Agree	Somewhat disagree
1. Course objectives were relevant to my needs	3	11	-
2. I was able to understand the content of the materials presented	2	12	-
3. Overall, the course was useful and will help me do my job better	7	7	-
4. There were enough practical exercises to facilitate understanding of the course	4	10	-
5. The pacing of sessions was appropriate for my understanding of course materials	4	10	-
6. The instructors were knowledgeable on the subject	4	10	-
7. The instructors allowed an appropriate level of participation in the class	6	8	-

Any other comments/suggestions:

1. Which topic(s) or aspect of the course should not be included in future workshops?

All topics are relevant to the aim of this training. They are very useful to my work. No part should be excluded in future trainings

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

- The action plan on next steps needs to involve the medicine regulatory authorities, the budget planning personnel, etc. so it should be discussed/developed at the first day of training when heads of PQCLDF & NQCLDF presented at meeting.
- The lab glassware used for training courses should be adequately provided along the class, so no need to wait the cleaned and dried glassware for the experiments
- Use USP RS and USP monographs on samples testing if sample's intensity is higher than 100%
- Give more time to explain sampling procedure

**List of Participants
Compendial Analysis of Antimalarial Medicines**

	Name	Institution	Location
1.	Else Dian Pramita, AMF	PQCLDF	Padang
2.	Gusnawati	PQCLDF	Padang
3.	KhusnulK Khotimah, S. Farm, Apt	PQCLDF	Yogyakarta
4.	Opsa Lena	PQCLDF	Yogyakarta
5.	Afinna Nurfitri Annandari, S. Farm, Apt	PQCLDF	Bandung
6.	Leni Maryati, S.Si	PQCLDF	Bandung
7.	Ni Putu Megawati, S. Si	PQCLDF	Denpasar
8.	Dra. Sri suryaniati, Apt., MM	PQCLDF	Denpasar
9.	Faridha Maera Lokana, A. Md	PQCLDF	Semarang
10.	Retno Hari Wahyuni, S. Farm., Apt	PQCLDF	Semarang
11.	Rozana, S.Si	NQCLDF	Jakarta
12.	Hetty Rieskaiana, S.si. Apt	NQCLDF	Jakarta
13.	Khusnul Wulansari, A. Md	NQCLDF	Jakarta
14.	Ratna Maritim, A. Md	NQCLDF	Jakarta
15.	Neni Isnaeni, S.Si., Apt	NQCLDF	Jakarta
16.	Fitra Budi Astuti, S.si., Apt	DGPPD	Ministry of Health, Jakarta

List of the training facilitators, who provided instrumental support and assistance

	Name	Designation	Department
1	Dyah Meita, S. Farm, Apt	Instructor	NQCLDF
2	Dra Rita Aritonang	Instructor	NQCLDF
3	Isnaini. S.Si	Instructor	NQCLDF

AGENDA

PQM Training Workshop

Evaluation of the Quality of 1st and 2nd-line Anti-tuberculosis Medicines by Full Compendial Testing Method

National Quality Control Laboratory of Drug and Food
National Institute for Health Research and Development
National Tuberculosis Program
Jakarta, Indonesia ♦ June 11-18, 2012

DAY 1 – Opening and Ethionamide Tablets: Identification and Assay

Time	Topic	Speaker
8:00-08:30	Opening Remarks	USAID, USP-PQM, BPOM
08:30-10:00	Introduction of the Workshop Introduction of Participants	Dr. Souly Phanouvong, USP-PQM ALL
10:00-10:15	Coffee/Tea Break	ALL
10:15-11:00	UV-Spectrophotometer: Calibration and practical aspects (lecture)	Dr. Yanga Kalambayi Dijiba, USP-PQM
11:00-12:00	Ethionamide Monograph Discussion Standard Preparation and Instrument Set-up	Dr. Yanga Kalambayi Dijiba, USP-PQM
12:00-13:00	Lunch	ALL
13:00-15:00	Ethionamide: Identification and Assay	ALL
15:00-15:15	Coffee/Tea Break	ALL
15:15-16:00	Ethionamide: Identification and Assay (continued)	ALL
16:00-17:00	Clean-up, Data Analysis and Conclude Day 1	Dr. Yanga Kalambayi Dijiba, USP-PQM

DAY 2 – Ethionamide Tablets: Dissolution

Time	Topic	Host
08:30-09:30	USP General Chapter <711> Dissolution	Dr. Yanga Kalambayi Dijiba, USP-PQM

09:30-10:00	Standard Preparation and Instrument Set-up for Dissolution Performance Verification Test (PVT)	ALL
10:00-10:15	Coffee/Tea Break	ALL
10:15-12:00	Dissolution Performance Verification Test	ALL
12:00-13:00	Lunch	ALL
13:00-15:00	Ethionamide Dissolution	Experiment
15:00-15:15	Coffee/Tea Break	ALL
15:15-16:00	Ethionamide Dissolution (continued)	Dr .Mark Liddell, USP Dr. Yanga Kalambayi Dijiba, USP-PQM
16:00-17:00	Clean-up, Data Analysis and Conclude Day 2	Participants with Guidance of USP, PQM

**DAY 3 – Rifampin, Isoniazid, Pyrazinamide, and Ethambutol Hydrochloride Tablets:
Assay (1)**

Time	Topic	Host
08:00-08:30	Rifampin, Isoniazid and Pyrazinamide Assay Discussion	Dr. Yanga Kalambayi Dijiba, USP-PQM
08:30-10:00	Rifampin, Isoniazid and Pyrazinamide Assay: Instrument Set-up	ALL
10:00-10:15	Coffee/Tea Break	ALL
10:15-12:00	Rifampin, Isoniazid and Pyrazinamide Assay: Standard Preparation and System Suitability Test	ALL
12:00-13:00	Lunch	ALL
13:00-15:00	Rifampin, Isoniazid and Pyrazinamide Assay: Standard Preparation and System Suitability Test (continued)	Dr. Yanga Kalambayi Dijiba, USP-PQM
15:00-15:15	Coffee/Tea Break	ALL
15:15-16:30	Rifampin, Isoniazid and Pyrazinamide Assay: Sample Preparation, Analysis Complete System Suitability Test	ALL
16:30-17:00	Clean-up, Conclude Day 4	Participants with Guidance of USP- PQM

DAY 4 – Rifampin, Isoniazid, Pyrazinamide, and Ethambutol Hydrochloride Tablets: Assay (2)

Time	Topic	Host
08:30-09:30	Rifampin, Isoniazid and Pyrazinamide Assay: (Additional runs) and Data Analysis	Dr. Yanga Kalambayi Dijiba, USP-PQM
09:30-10:00	Ethambutol HCl Assay Discussion and Instrument Set-up	Dr. Yanga Kalambayi Dijiba, USP-PQM
10:00-10:15	Coffee/Tea Break	ALL
10:15-12:00	Ethambutol HCl Assay: Standard Preparation and System Suitability Test	ALL
12:00-13:00	Lunch	ALL
13:00-15:00	Ethambutol HCl Assay: Sample Preparation and Analysis	ALL
15:00-15:15	Break	All
15:15-16:00	Clean-up, Data Analysis	ALL
16:00-17:00	Open Discussion on 4FDC method Conclude Days 4 and 5	Dr. Yanga Kalambayi Dijiba, USP-PQM

DAY 5 – Levofloxacin Tablets: Assay

Time	Topic	Host
08:00-08:30	Levofloxacin Monograph Discussion	Dr. Yanga Kalambayi Dijiba USP-PQM
08:30-10:00	Levofloxacin Assay: Standard Preparation and Instrument Set-up	ALL
10:00-10:15	Coffee/Tea Break	ALL
10:15-12:00	Levofloxacin: System Suitability Test and Sample Analysis	ALL
12:00-13:00	Lunch	ALL
13:00-15:00	Levofloxacin Assay: Data Analysis	ALL
15:00-15:15	Coffee/Tea Break	ALL
15:15-16:45	Aminosalicylic Acid: Identification	ALL
16:45-17:00	Clean-up, Conclude Day 5	Dr. Yanga Kalambayi Dijiba USP-PQM

DAY 6 – (Para) Aminosalicyclic Acid Tablets (PAS): Assay

Time	Topic	Host
08:30-09:00	Aminosalicyclic Acid Monograph Discussion	DrYanga Kalambayi Dijiba, USP,, PQM
09:00-10:00	Aminosalicyclic Acid Assay: Standard Preparation and Instrument Set-up	ALL
10:00-10:15	Coffee/Tea Break	ALL
10:15-12:00	Aminosalicyclic Acid Assay: System Suitability Test	ALL
12:00-13:00	Lunch	ALL
13:00-15:00	Aminosalicyclic Acid Assay: Sample Preparation and Analysis	ALL
15:00-15:15	Coffee/Tea Break	All
15:15-16:15	Data Analysis	Dr. Yanga Kalambayi Dijiba, USP, PQM
16:15-17:00	Clean-up and Instrument Wash/Shutdown	ALL

DAY 7 – Data Compilation, Open Discussion, Q&A, and Closing

Time	Topic	Host
08:30-10:00	Conclude week 1 Data compilation, review	Dr. Yanga Kalambayi Dijiba, USP,PQM
10:00-10:15	Coffee/Tea Break	ALL
10:15-12:00	Discussion: Data handling, report generation and investigating out-of-specification results	Dr. Yanga Kalambayi Dijiba, USP, PQM
12:00-13:00	Lunch	ALL
13:00-15:00	Open Discussion Future Plans Q&A	Dr. Yanga Kalambayi Dijiba,USP, PQM
15:00-15:15	Coffee/Tea Break	All
15:15-17:00	Closing Ceremony and Certificates	ALL

Evaluations by Participants
 PQM Training Workshops
 Evaluation of Quality of 1st and 2nd Line Anti-TB Medicines
 by Full Compendial Testing Methods

Jakarta, Indonesia June 11-18, 2012

Overall Evaluation of the Training Workshop

	Strongly agree	Agree	Somewhat disagree
1. Course objectives were relevant to my needs	3	11	-
2. I was able to understand the content of the materials presented	1	13	-
3. Overall, the course was useful and will help me do my job better	6	8	-
4. There were enough practical exercises to facilitate understanding of the course	2	12	-
5. The pacing of sessions was appropriate for my understanding of course materials	2	12	-
6. The instructors were knowledgeable on the subject	8	6	-
7. The instructors allowed an appropriate level of participation in the class	4	10	-

Any other comments/suggestions:

1. Which topic(s) or aspect of the course should not be included in future workshops?

Lecture (theory part) is too long and a little bit hard to understand

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

- Add more time for trainees to practice
- Provide translator/interpreter during the training for non-English speaking participants
- Recommend to include Cetirizine monograph into next training
- Stick to original set training schedule without too much change/modification
- All PQCLDF staff should be given this training since it is very important skill
- It would be better to have training material hand-out sent to trainees ahead of training start