

USP DQI and Medicines Transparency Alliance Training on Basic Tests using Minilabs® in Kyrgyzstan

Bishkek, Kyrgyzstan

September 14-18, 2009

Trip Report

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About USP DQI

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

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

Abstract

USP DQI, in collaboration with Medicines Transparency Alliance (MeTA), offered a training workshop on medicines sampling, visual and physical inspection, Thin Layer Chromatography, and simple disintegration at the Kyrgyzstan Department of Drug Provision and Medical Equipment (DDPME) laboratory in Bishkek, September 14-18. The training was attended by nine individuals, of whom 6 were Kyrgyzstan DRA staff members and 3 represented the Kyrgyzstan private sector.

The training was done by two USP trainers working in collaboration with the MeTA team.

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Key Words

Medicines, Quality Control, Quality Assurance, Minilab[®], TLC, fake, counterfeit medicines, substandard medicines, sampling.

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The authors are grateful to the Director General of the Department of Drug Provision and Medical Equipment, Mr. Rustam A. Kurmanov; his Deputy, Dr. Djanyl Djusupova (who is also a staff of MeTA); and all other staff from the QC lab for their time and assistance during the training.

Finally, the authors would like to thank Dr. Damira Bibosunova, USAID/Kyrgyzstan Project Manager, and Mr. Anthony Boni and Ms. Veerle Coignez at USAID Washington for their guidance and helpful insights throughout the preparation stages of this training.

ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
CIS	Commonwealth of Independent States
DDPME	Department of Drug Provision and Medical Equipment
DQ	Drug Quality
DRA	Drug Regulatory Authority
HIV	Human Immunodeficiency Virus
HPLC	High Performance Liquid Chromatography
MeTA	Medicines Transparency Alliance
QA /QC	Quality Assurance / Quality Control
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information

Background

Kyrgyzstan is a landlocked, mountainous country bordering Kazakhstan, Uzbekistan, Tajikistan, and China with a population of about 6 million. The country gained independence in 1991 and is considered one of the poorest countries in the region.

About ninety-seven percent of drugs in Kyrgyzstan are imported¹, mainly from Russia and the Commonwealth of Independent States. The Department of Drug Provision and Medical Equipment (DDPME), established under the Ministry of Health in 1997, is the drug regulatory authority (DRA). It is responsible for implementing the national drugs policy, the registration and licensing of locally produced and imported drugs, vaccines and medical products, the quality assurance of drugs, and the monitoring of drug use.

The Department of Drug Supply and Medical Equipment administers the Central Analytical Quality Control Laboratory, which was created in 1996 to examine the quality of drugs. The current systems in place are inadequate to ensure and monitor quality of medicines in the country.

USP DQI, in collaboration with Medicines Transparency Alliance (MeTA), offered a training workshop on medicines sampling, visual and physical inspection, Thin Layer Chromatography, and simple disintegration at the Kyrgyzstan DRA laboratory in Bishkek, September 14-18. The training was attended by nine individuals, of whom 6 were Kyrgyzstan DRA staff members and 3 represented the Kyrgyzstan private sector.

The training was done by two USP trainers working in collaboration with the MeTA team.

Purpose of Trip

Following MeTA's request for USP DQI to offer training for Kyrgyzstan's DRA staff on the use of basic tests, USP DQI organized this trip to Bishkek to:

1. Train DRA and MeTA staff to become trainers on basic tests using Minilabs[®]
2. Train trainers on drug sampling, visual and physical inspections, TLC, and simple disintegration
3. Assist trainers and MeTA staff set up a drug quality monitoring program tailored to the Kyrgyzstan situation
4. Train participants on data management and sharing

Source of Funding

This trip was funded by MeTA with contributions from USP DQI, through Core funding for Common Agenda.

¹ Medicines Prices, Availability, Affordability and Price Components in Kyrgyzstan: (2005) Report of Drug Information Center-Department of Drug Provision and Medical Devices. Bishkek – Kyrgyzstan.

Overview of Activities

Venue of the training: The Quality Control Laboratory of the Department of Drug Provision and Medical Equipment (DDPME) – Bishkek

Participants: See *Annex 1*

Medicines Tested by Minilab[®]: Acetyl salicylic acid, Paracetamol, Amoxicillin, Ampicillin, Glibenclamide, Metronidazole, Aminophylline, Sulfamethoxazole, Isoniazid, and Rifampicin

Training Modules: Medicines sampling, visual and physical inspection of medicine packages and dosage forms, Thin Layer Chromatography, simple disintegration, and data management and reporting

Training Schedule

Sunday, Sept 13, 2009

The USP DQI team met with MeTA local staff (Baktugul Toktobaeva, Suluke Abakirova, and Djanyl Djusupova) at their offices to discuss plans for the training and to review the training manuals translated from English to Russian by MeTA. The USP DQI team informed MeTA colleagues about what would be needed for the first day of the training.

Monday, Sept 14, 2009

The USP DQI team met with the Director General of the Department of Drug Provision and Medical Equipment (DDPME), Mr. Rustam A. Kurmanov, and his Deputy, Dr. Djanyl Djusupova. The Director welcomed the USP DQI team and expressed his satisfaction regarding conducting the training in his laboratory. The Director gave an overview of the functions of his department and the challenges faced because of the lack of resources. Dr. Djanyl Djusupova welcomed the USP DQI team and gave a brief background about the MeTA project in Kyrgyzstan as well as the pharmaceutical situation in the country. She also expressed her wish to extend the collaboration with USP DQI because the department is in need of technical assistance in the areas of drug registration, quality control, and drug safety in general.

Dr. Smine gave an overview about DQI's mandate and services and how the program works to provide assistance to USAID-supported countries. Dr. Burimski translated and assisted Dr. Smine answer questions during the meeting. Mr. Kurmanov and Dr. Djusupova were interested to learn how DDPME could benefit from DQI technical assistance. Dr. Smine and Dr. Burimski responded to all their questions.

Opening Ceremony

Mr. Kurmanov welcomed the participants, trainers, and MeTA staff and gave a short address focusing on the importance of this training for the country. He asked the participants to be dedicated and learn as much as they can because they will be responsible for implementing the first ever drug quality monitoring program in selected pilot areas of Bishkek and other regions.

Dr. Smine thanked the MeTA and DDPME staff who worked hard in organizing and preparing for the training and then gave an overview about the training program for the week. He also mentioned that DQI has a long history of implementing similar programs in many countries around the world and that the training will be the best opportunity for MeTA and DDPME staff to learn from other experiences.

Presentations

After the opening ceremony, the training officially started. Dr. Burimski talked to the participants about activities/projects that USP has been involved with in the Commonwealth of Independent States (CIS). Dr. Smine gave a presentation on drug quality assurance and discussed all of the definitions related to the program. He also gave an overview about assuring the quality of medicines from manufacture to their use by the patient.

In the second presentation, the USP DQI team focused on quality control of medicines and the rationale of using basic tests in countries with limited resources. They discussed some of the success stories regarding the approach of using basic tests as a first line of defense against the threat of counterfeit and substandard medicines.

A third presentation covered examples of packages of fake medicines from South East Asia. This presentation helped the trainees with visual inspection of all information that must be written on any drug package.

At the end of day, USP DQI staff introduced the Minilab[®] to the participants and went through all its components. The USP DQI team took this opportunity to instruct participants on how they should handle the reagents and other supplies. They also covered the basic safety measures that users should comply with when using the Minilab[®]. The training room was set up for two groups, each with one new Minilab[®].

The USP DQI team discussed basic information about TLC as an analytical method, including its advantages and limitations. They prepared a blue solution and instructed the participants in an exercise on spotting on a paper filter because this step is considered the critical step in learning how to carry out proper TLC analysis.

Tuesday, Sept 15, 2009

The first two TLC runs were conducted in a step-by-step manner to allow the trainees to learn the good practices in each step. The trainees were asked to follow the translated protocols and the USP DQI team assisted the trainees when necessary.

The first day, the group was able to carry out full TLC analysis of aspirin (acetyl salicylic acid) and Paracetamol using several samples of each. Samples used for the training were purchased from within the country.

Wednesday, Sept 16, 2009

Two TLC runs were conducted in the morning (amoxicillin and ampicillin), and two more were conducted in the afternoon (isoniazid and rifampicin).

Thursday, Sept 17, 2009

Two TLC runs were conducted in the morning (glibenclamide and metronidazole), and two more were conducted in the afternoon (aminophylline and sulfamethoxazole). All samples tested since Wednesday underwent visual and physical inspection before each TLC test. At the end of the day the participants, were trained on how to carry out simple disintegration according to the Minilab[®] protocol, but used three separate tablets per test instead of five.

Friday, Sept 18, 2009

The USP DQI team instructed the trainees on medicines sampling and different sampling approaches, emphasizing the importance of sampling as the critical part of any drug quality monitoring program. The team provided MeTA staff with USP DQI sampling guidelines and explained that they should implement a sampling strategy that takes Kyrgyz issues into consideration.

The USP DQI team also focused on the three-level testing program and emphasized the necessity of a strong QC laboratory to follow up and monitor the Minilab[®] activities. They shared the USP DQI testing and data reporting guidelines.

The participants received certificates of training in the use of basic tests using Minilabs[®]. The USP DQI team expressed their hope that other opportunities for collaboration will come in the future, and Dr. Djanyl Djusupova offered her sincere thanks to USAID, USP DQI and MeTA for sponsoring the training.



Training participants

Next steps

- MeTA Kyrgyzstan will implement the use of basic tests in a pilot area in the suburbs of Bishkek and other regions
- USP DQI offered to assist MeTA by reviewing the study protocol, when available
- USP DQI will assist the DDPME if they request technical assistance from USAID
- USP DQI will share the trip report with USAID and MeTA

Conclusion

The Training Workshop was successful and met the intended objectives. The participants were dedicated and showed interest in learning about all aspects of the training program. They are now qualified trainers and able to train others.

USP DQI had great interaction with the heads of DDPME. This institution is a key player in drug quality assurance in Kyrgyzstan and is in urgent need of technical assistance and training. USP DQI staff promised to assist DDPME as much as they can and urged the heads of DDPME to benefit from other national and regional programs and to put the need for technical assistance as a priority in order to address the gaps in the pharmaceutical sector.

USP DQI staff briefed the USAID program manager in Kyrgyzstan about the training offered in Bishkek.

ANNEX 1

List of Participants

	Name	Title		Contact information
1.	Suluke Abakirova	Technical assistant	Nat MeTA Secretariat	tel/fax: +996 312 900 411 asuluke@yahoo.com
2.	Ayzada Batyrbekova	Analyst	Quality Control Lab of Drug Department	tel. +996 312 542931, mob: +996 700 078585
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6.	Sadibar Kutbaeva	Head of QCL	South Branch of Drug Department, Osh	tel. +996 3222 32994 mob. +996 772 240186
7.	Erkina Mailykova	Deputy head of QCL	Quality Control Lab of Drug Department	tel. +996 312 542931, mob: +996 552 220273
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9.	Svetlana Li	Manager	"Adilet pharm", Jalalabad	tel. +996 372256981 jalmukr@mail ru

MeTA Secretariat

1.	Djanyl Djusupova	Co-coordinator	Nat MeTA Secretariat	tel. +996 312 543230 ddjanyl@gmail.com
2.	Mariam Djankorozova	Co-coordinator	Nat MeTA Secretariat	tel.+996 312 663960 mariamkad@gmail.com
3.	Suluke Abakirova	Technical assistant	Nat MeTA Secretariat	tel/fax: +996 312 900 411 asuluke@yahoo.com
4.	Baktygul Toktobaeva	Technical assistant	Nat MeTA Secretariat	tel/fax: +996 312 900 411 baktyguld@gmail.com

Evaluation by Participants

Name of session: USP DQI and MeTA Training on Basic Tests using Minilabs® in Kyrgyzstan

Participants are given evaluation forms at the beginning of each module of the training workshop and asked to rate its educational materials and associated activities. Participants are asked to rate all categories that apply and return the completed form to the instructor.

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

Any other comments/suggestions:

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

- Conduct a short presentation/session on safety procedures while doing Minilab
- Conduct a short presentation/session on basics of TLC for participants with no lab experience (1)
- Conduct a short session on laboratory waste disposal (1)
- Include sampling of the medicines (for example, at the black market) in the course (2)
- Conduct training on HPLC, GLC, etc.(2) and fake medicines should be tested during the training (1)
- Correct errors in the Russian translation of the monographs from the Minilab Manual (1)
- The course should last longer (1)
- Methods to test injectable medicines should be developed (1)
- Liked the course very much (2); thank you for conducting such an unforgettable course (1)

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

- It would be interesting to see how laboratory personnel work in USA (1)
- Most of the reference standards in the Minilab consist of only 20 tablets. It would be good if there were more (1)
- Recommend to Global Pharma Health Fund adding additional pipettes to Minilab which would allow for expediting the tests (1)
- There should be a picture of how Minilab supplies are supposed to be situated in the case so it would be easy to put them back where they belong (1)